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): April 10, 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 7.01 Regulation FD.

On April 10, 2023, QSAM Biosciences, Inc. (the "Company") posted an updated corporate presentation on its website, a copy of which is being furnished as Exhibit 99.1 to this report and incorporated herein by reference. The Company may use the presentation, 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 presentation is 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.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

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

Exhibit Number	**Description**

99.1	QSAM Biosciences, Inc. corporate presentation, dated April 10, 2023.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document).

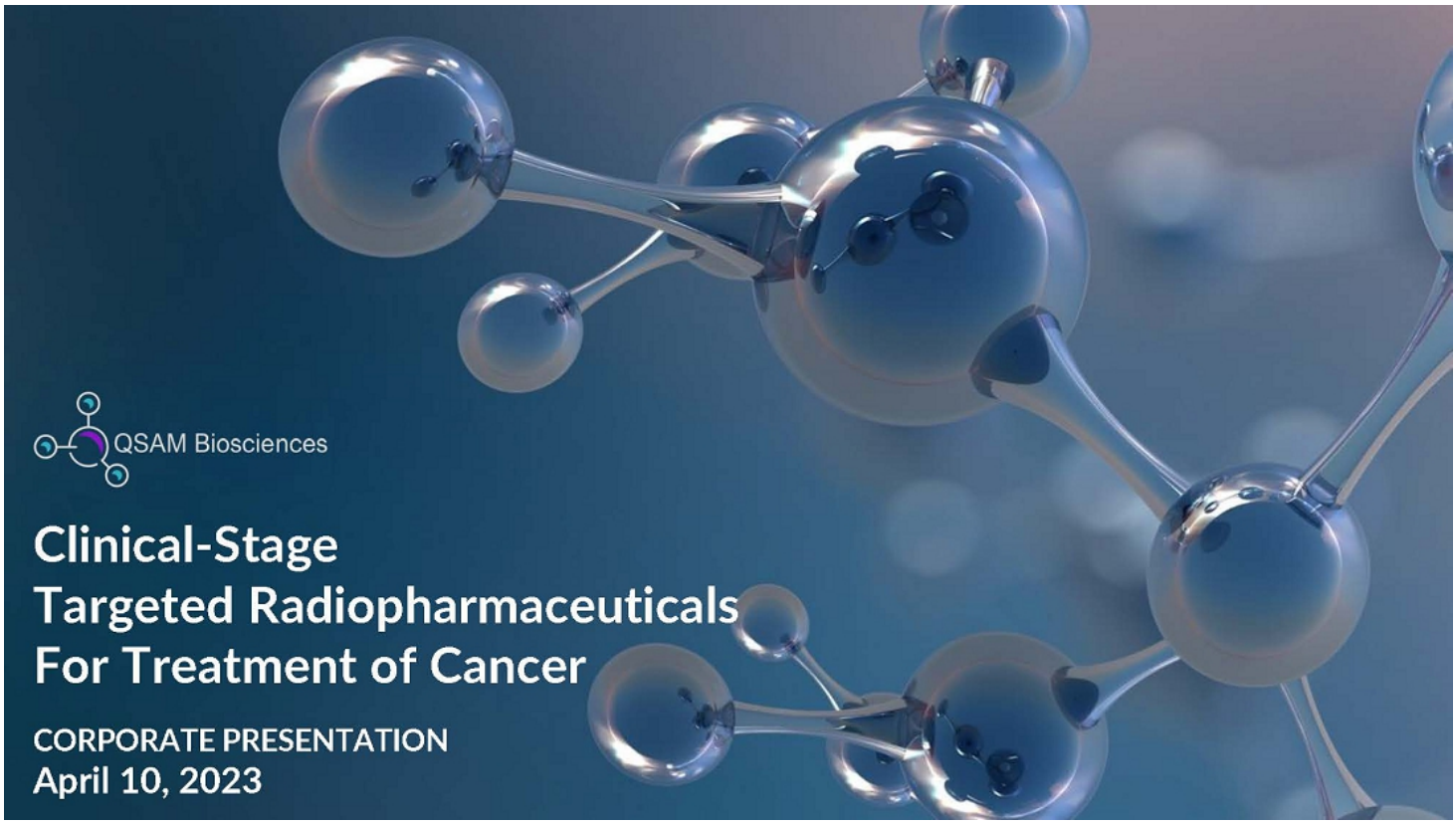
Signatures

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: April 11, 2023

QSAM Biosciences, Inc.

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



Forward Looking Statements

QSAM Biosciences

This document contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties and are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements are based upon current plans, estimates and expectations that are subject to various risks and uncertainties. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as "anticipates," "believes," "hopes," "estimates," "looks," "expects," "plans," "intends," "goal," "potential," "may," "suggest," and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts are forward-looking statements.

Among other factors that could cause actual results to differ materially from those expressed in forward-looking statements are QSAM Biosciences ("QSAM") need for, and the availability of, substantial capital in the future to fund its operations and research and development; the fact that QSAM's therapeutics may not successfully complete pre-clinical or clinical testing, or be granted regulatory approval to be sold and marketed in the United States or elsewhere. A more complete description of these risk factors is included in QSAM's filings with the Securities and Exchange Commission (sec.gov). Readers are urged to consider all factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements. Readers should also carefully review the risk factors described in other documents that QSAM files from time to time with the Securities and Exchange Commission. The forward-looking statements in this document speak only as of the date of these materials. Except as required by law, QSAM assumes no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

QSAM Biosciences
Developing *Next-Generation Targeted Radiopharmaceuticals* for Treatment of Cancer

Initial Lead Asset
Clinical stage bone seeking cancer therapeutic with precedent for safety, efficacy and FDA approval.

Recent Milestones
First Cohort Completed in Phase 1 Clinical Trial; Multiple sites opened; Orphan and Rare Pediatric Disease Designation granted by FDA.

Market Potential
Multiple multi-billion dollar underserved market indications; Market and usage differentiation from approved peers.

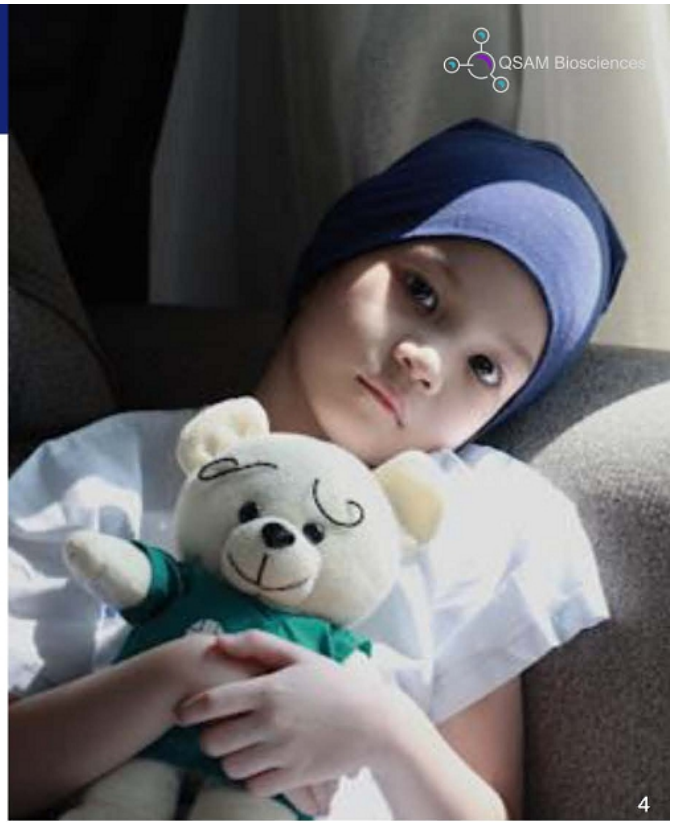
Leadership
Experienced management and Board with successful record of FDA approvals, big pharma partnerships and M&A.

Opportunity
Attractive valuation entry point with near term inflection points and exit potential in rapidly growing nuclear medicine sector experiencing accelerating big pharma activity.

Bone Cancer is High Unmet Need with Significant Market Potential

Bone Metastasis Breast, Lung, Prostate (others)	Osteosarcoma & Ewings Sarcoma
400K New Cases US[1] >50% of cancer results in bone metastasis[2]	**~1,200** New Cases[3] MOSTLY **PEDIATRIC**
350K Deaths US[1] Standard of Care Not Effective	**Limb Amputation Frequent** **No material treatment advances in** **40 yrs**
$20B TAM Using competitive pricing	**$125M TAM US** $100M value of Rare Pediatric Voucher

1. Huang, J., et al., 2020. Incidence Of Patients With Bone Metastases At Diagnosis Of Solid Tumors In Adults: A Large Population-Based Study.
2. Cleveland Clinic Journal of Medicine July 2022, 89 (7) 393-399; DOI: https://doi.org/10.3949/ccjm.89a.21062
3. Key Statistics for Osteosarcoma (cancer.org)



CycloSam® [Samarium-153 DOTMP]

QSAM's Next-Generation Therapeutic Radiopharmaceutical Targeting Treatment of Bone Cancer

"TACTICAL NUCLEAR WARHEAD" - SAMARIUM-153

- New formulation of previously FDA approved isotope
- Published human data in prior clinical study (550+ patients) indicates repeated dose is ~73% effective in treatment of bone tumors*

+

BONE TARGETING "MISSILE" - DOTMP

- Seeks high mineral turnover at and around site of bone tumors
- Significant animal studies and three human patients indicate preliminary safety and effectiveness of delivery

* 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.

Material Precedent of Efficacy for Treating Bone Cancer

Dr. Helmut Sinzinger's Vienna Protocol using prior Samarium-153 formulation

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Multiple Dosing of Sm-153-EDTMP (prior drug formulation)

- **550+ Patients**; prostate and breastbone metastases
- Repeated low doses @ 3-month intervals

Positive Clinical Response

73% of patients – positive clinical response

64% of patients – significant regression

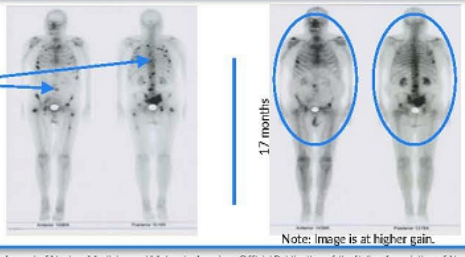
Prolonged Survival up to 5 years

Challenges with Sm-153-EDTMP (prior drug formulation)

- Accumulation of radioactive, long-lived impurities
- Inhibits multi-dosing & combination with chemotherapy
- Not viable for clinical treatment of bone cancer

Prostate Patient after 5 Treatments

Dark spots are sites of metastatic disease



Most dark spots gone; weight gain & thriving

Note: Image is at higher gain.

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.

We believe CycloSam® Overcomes Therapeutic & Manufacturing Limitations of Prior FDA-Approved Samarium-153

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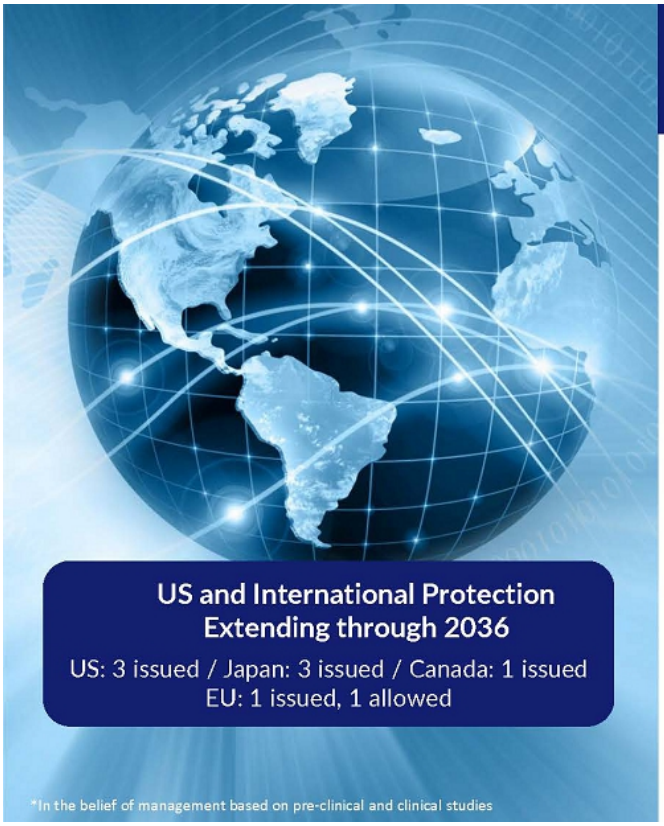
Limitations of Prior Drug	Improvements over Prior Drug	Clinical Objectives*
Toxicity: adverse side-effects	Patented improvement in manufacturing eliminates nearly all long-lived impurities	Higher & Multi-Dose regimen possibilities*
Saturation: difficulty using multi-dose	New chelating agent delivers more payload to tumor site	Potential Disease Modifying Effects*
Availability: hard to produce	Patented process simplifies production and reduces costs	New Indications Larger Markets*

*Clinical objectvies are goals and not yet proven through clinical data; all improvements must be tested in clinical trials.



Improvements Covered by Intellectual Property Portfolio

14 patents across 3 distinct patent families

- **Use of "lower specific activity" Sm-153**
  - Lower toxicity, higher availability
  - Covers novel production of radioisotope key to assumptions of safety and efficacy
- **Kit for nuclear pharmacy preparation of CycloSam®**
  - More streamlined preparation & delivery at lower costs
- **Repeated dosing regimens**
  - Potential for significant disease modification*

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Corporate Strategy & Investment Thesis

CycloSam® Pathway to Value Creation and Potential Exit for Shareholders

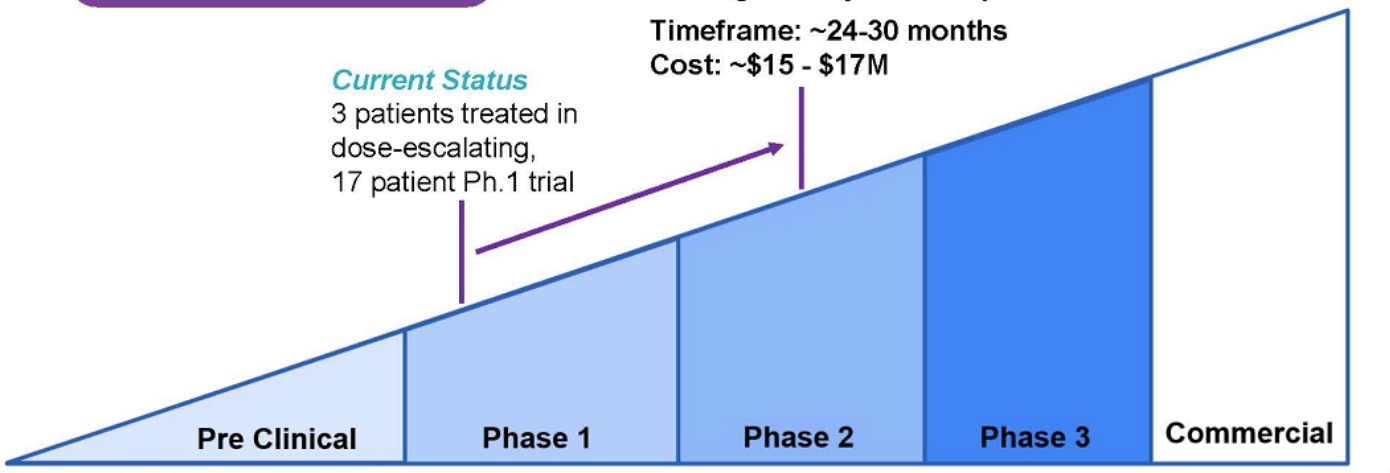
QSAM Biosciences

QSAM may seek to partner with global pharma company upon achieving Primary Clinical Objective

Primary Clinical Objective
Demonstrate tumor efficacy; similar or better results than prior Sinzinger study in 20-30 patients

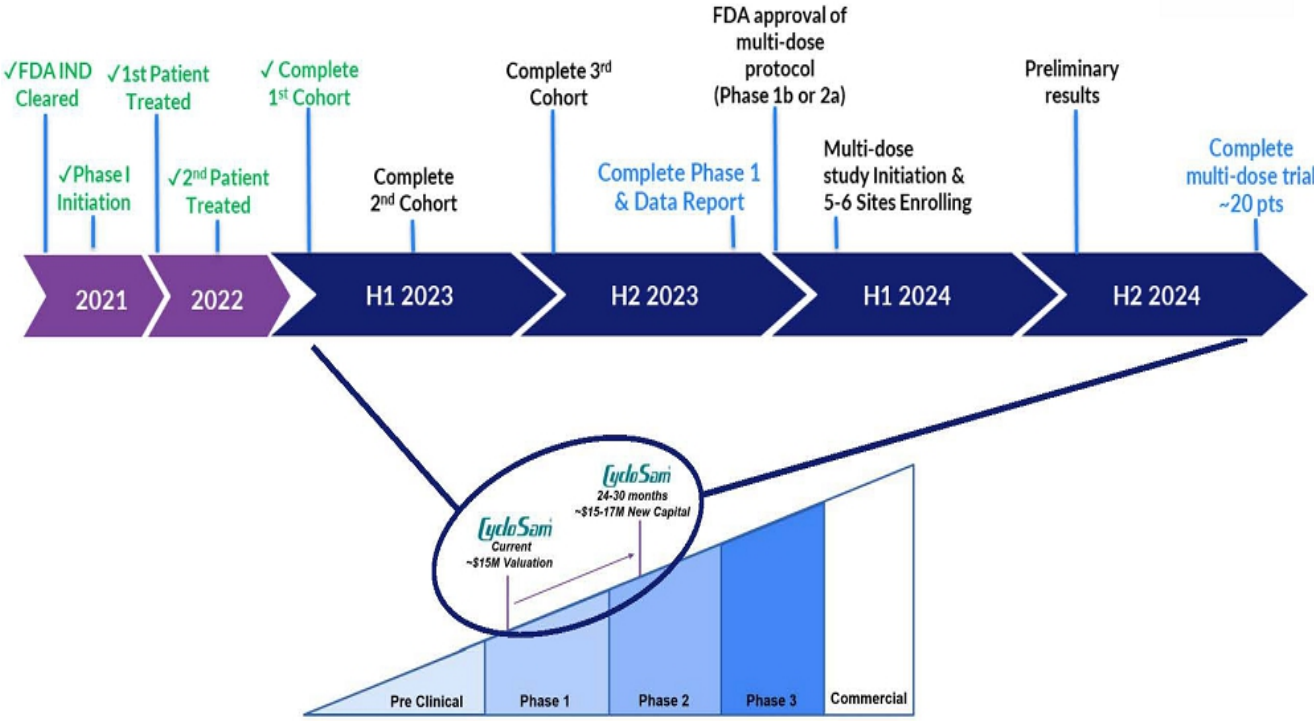
Timeframe: ~24-30 months
Cost: ~$15 - $17M

Current Status
3 patients treated in dose-escalating, 17 patient Ph.1 trial



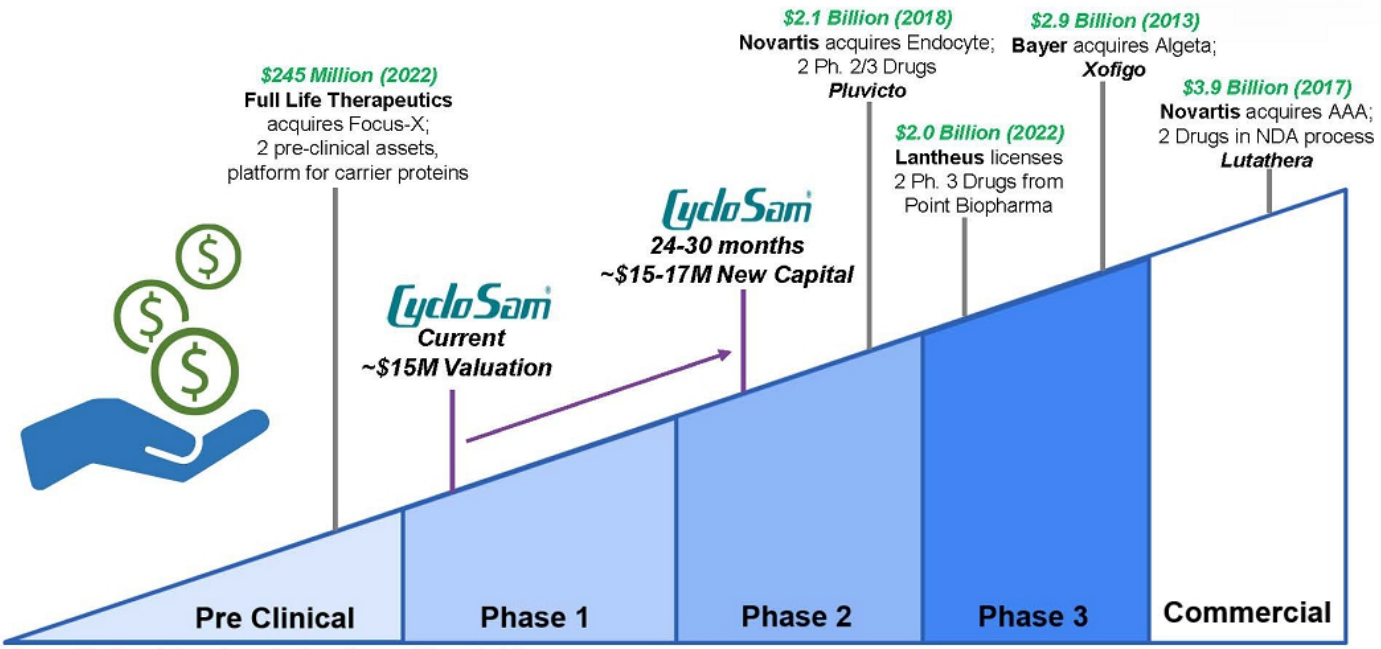
Forward looking statements – actual results may differ materially.

Near-Term Milestones & Value Inflection Points



Forward looking statements – actual results may differ materially.

CycloSam® Potential Value based on Deal Comps



Forward looking statements – actual results may differ materially.

Public Market Comps Support Opportunity for Significant Valuation Appreciation

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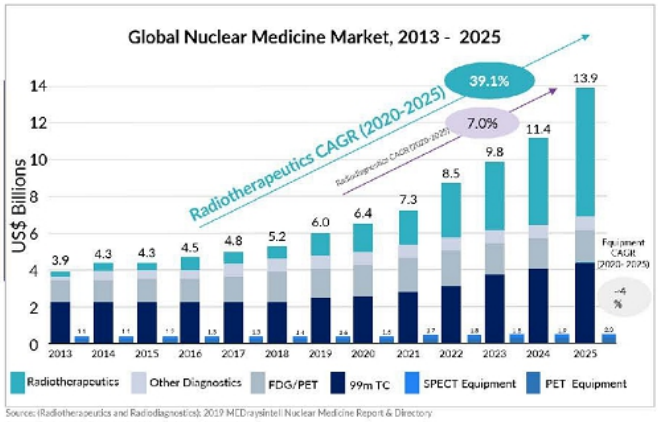
Company	Transactions	Clinical Asset(s)	Stage	Market Cap*
Fusion Pharmaceuticals Inc.	R&D Partnership AstraZeneca	One/Alpha Prostate	Phase I	Nasdaq: FUSN $160M
AlphaTAU	2021 SPAC Transaction Israeli Corp.	Multiple Skin, Oral, Prostate	Phase I/II	Nasdaq: DRTS $285M
Actinium Pharmaceuticals, Inc.	Partnerships: astellas AVEO ONCOLOGY	One/Alpha Leukemia/Stem Cell Transplant	Phase II/III	NYSE: ATNM $272M
POINT BIOPHARMA	Partnerships and Investors: LANTHEUS Johnson & Johnson INNOVATION	Two/Beta Prostate and Gastro	Phase III	Nasdaq: PNT $780M

* Public information as of *Janaury 19, 2023*

Radiopharmaceuticals are Exciting, New Sector in Cancer Therapy

Radiopharmaceutical sector seeing exponential growth



Source: (Radiotherapeutics and Radiodiagnostics): 2019 MCDraysintell Nuclear Medicine Report & Directory
Source (Equipment): Siemens | healthineers Molecular Imaging

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Big Pharma making multi-billion investments in sector and bringing new therapies to market

Company	Drug / Launch	Indication	Sales
BAYER	Xofigo 2013	Prostate	Peak 2017 - $464M
NOVARTIS	Lutathera 2018	Gastro-intestinal	2020 - $445M
NOVARTIS	Pluvicto 2021	Prostate	Q3 2022 - $80M Est. $2B 2 yrs.

Commercial Comparable: Xofigo®

First well-known radiopharmaceutical

QSAM Biosciences

About Xofigo	Key Takeaways
Xofigo approved with patient survival improvement of 3 months	Low Bar to Approval
$69,000 - $82,800 (6 doses/4-week intervals)	High Comparable Pricing
$464M+[1] sales in 2017	Substantial Sales Despite Limited Specific Indication
Commercialization & development rights acquired by Bayer for ~$800M in 2009	Significant Valuation Opportunity

Source: Xofigo Website

Indicated for castration resistant prostate cancer

	CycloSam® Sm-153 (β particle)	Xofigo® Ra-223 (α particle)
Half-Life	46 hours	11.2 days
Tissue Penetration	3 mm	0.1 mm
Side Effects	Negligible*	Significant

1. Bayer Annual Report 2019 (amazonaws.com)

** In the belief of management based on pre-clinical and clinical studies*

Commercial Comparable: Pluvicto®

Recently Approved; Strong Regulatory and Commercial Precedent for CycloSam®

QSAM Biosciences

About Pluvicto	Key Takeaways
Indicated PSMA-positive metastatic castration-resistant prostate cancer (mCRPC)	Limited Patient Population • Male • Adult • 80% of mCRPC • Late-line therapy
FDA-approved with overall survival improvement of 4 months	Low Bar to Approval
$255,000 treatment cost $42,500 per dose (6 doses/6-week intervals	High Comparable Pricing
$2B+ peak sales expectations	Substantial Sales Opportunity Despite Limited Indication & Patient Population

PLUVICTO Website states:

	CycloSam® Samarium 153 DOTMP	Pluvicto® Lutetium Lu 177 vipivotide tetraxetan
Radioisotope	^{153}Sm	^{177}Lu
Half-Life	1.9 days	6.6 days
Emission	β^-	
Max β Energy: (Mev)	0.81	0.489
Tissue Penetration	3mm	2mm

Targeted Palliative Radionuclide Therapy for Metastatic Bone Pain

Liu, Angus. "Novartis CEO: Leqvio, Pluvicto off to Solid Starts, but Blockbuster Sales Will Take Time." *Fierce Pharma*, 26 Apr. 2022

QSAM Biosciences

Leadership & Capitalization

Results-Driven Management Team

Successful FDA approvals, Fundings, M&A and Exits

QSAM Biosciences

Douglas Baum
CEO, Co-Founder, Director
30 years successful drug development. Former CEO at Xeris Pharmaceuticals. Muliple FDA/EMA approvals.

C. Richard Piazza, PhD
Exec. Chairman, Co-Founder, Director
40+ years experience in med. devices, biotech and pharmaceuticals. 4 successful exits.

Adam King
CFO
Founder of consulting group for large private equity-backed international companies to CFO of small start-ups.

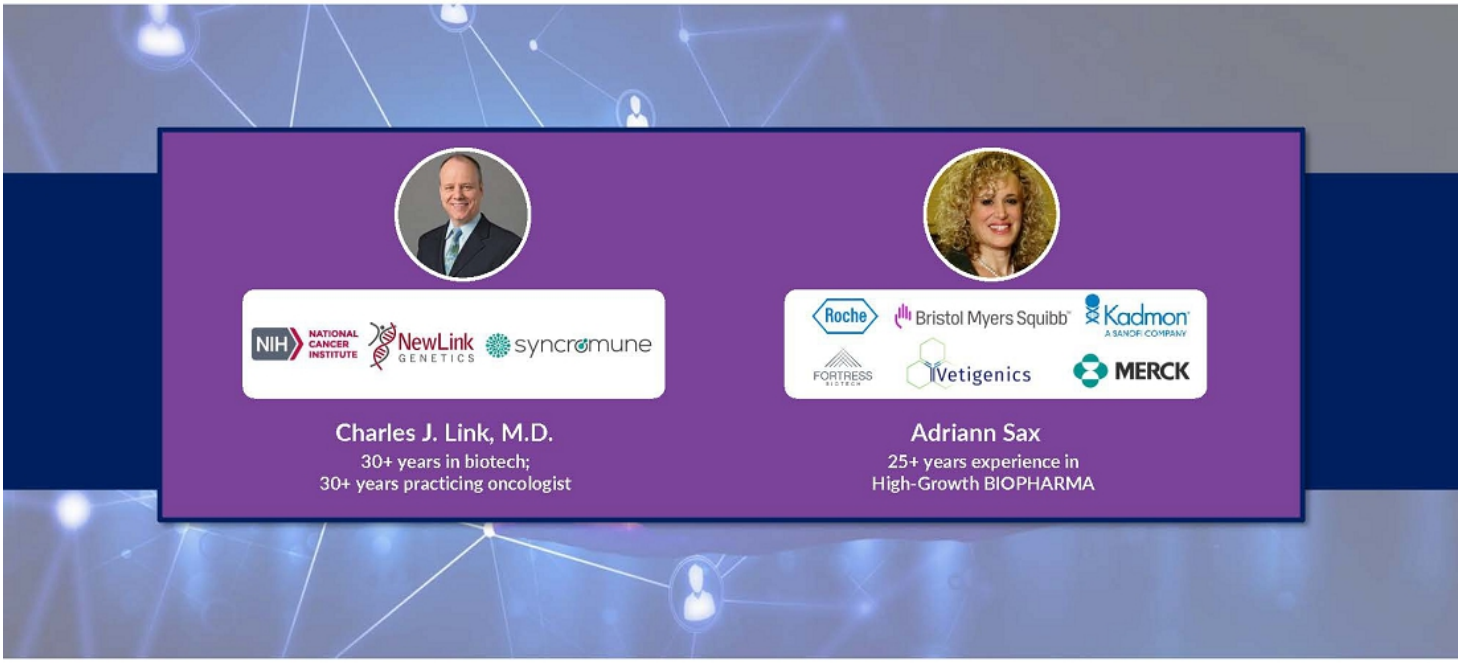
Christopher Nelson
General Counsel
25+ years in finance and M&A; 4 successful Nasdaq/NYSE go-public transactions in last 5 years.

Barry Sugarman
Regulatory & Clinical
30+ years in pharmaceutical, medical device development, manufacturing, clinical trials & regulatory affairs.

Namrata Chand
VP Operations
20 years of healthcare industry experience in multiple key functions including operations, business development and marketing

Accomplished Independent Directors

QSAM Biosciences



Leading Scientific & Clinical Teams

QSAM Biosciences

World-renowned Authorities in Radiopharmaceuticals

R. Keith Frank, PhD

Jim Simón, PhD

- Developers of CycloSam® and Quadramet®
- Founders of IsoTherapeutics – radiopharmaceutical R&D and manufacturing service company for big and small pharma
- Collectively, 70+ years with Dow Chemical Company
- 60+ Patents; 100+ scientific papers

DOW

IsoTherapeuticsGroup,LLC
Radiopharmaceutical R&D and Manufacturing

Efficient Use of Capital – Significant Recent Accomplishments

QSAM Biosciences

Since April 2020 utilizing under $5M in funding, management has made significant progress

Strategic-Financial

- Raised ~$5M – Common Stock, Preferred and Convertible Note offerings

R & D

- Product stability, validation and performance completed (Impurities study - negligible)
- Established primary reactor for Sm-153 production; qualifying 3 add'l reactors
- Cold kits manufactured and stocked
- Supply Chain in place

Clinical & Regulatory

- FDA cleared IND to address multi-billion dollar bone mets market (Aug '21)
- First 3 patients successfully treated in Phase I Bone Mets trial
- Orphan Drug Designation granted (Aug '21)
- Rare Pediatric Disease designation granted (Jan '22)

Corporate

- Option for 2nd radiopharmaceutical obtained (Mar '21)
- Assembled experienced management team
- Added 2 accomplished independent Board members

Cap Table

QSAM Biosciences

QSAM Cap Table as of 3-31-23	Outstanding	Avg. Conv. Price
Common Shares (1)	3,014,805	-
Preferred Shares (2)	517,722	$4.75
Convertible Notes (3)	-	-
TOTAL FUNDED SHARES	3,532,527	
Warrants	50,000	$6.00
Employee Options	177,815	$12.57

✓ Management Ownership: ~24% of FD

(1) Includes exercise of warrants and conversion of notes, per Form 8-K filed 4-4-23
(2) Includes Series A and B preferred shares with accrued dividends through 3/31/23
(3) All notes retired as of 3/31/23, per Form 8-K filed 4-4-23

QSAM Biosciences

Clinical Trials and Data

Impactful Preclinical Studies for CycloSam® - Real-World Evidence

QSAM Biosciences

Toxicology

Sprague-Dawley rats & Beagle dogs

- No systemic toxicity with single IV dose of non-radioactive 153Sm-DOTMP
- No saturation effect at high doses

IsoTherapeuticsGroup,LLC
Radiopharmaceutical R&D and Manufacturing

Proof of Concept Study (Real-World Data)

Canine osteosarcoma & bone mets; 9 dogs

- Uptake in tumor for all dogs
- Half myelotoxicity than Quadramet®; potential combination with chemotherapy

College of Veterinary Medicine
University of Missouri

Dose Escalation Trial (Real-World Data)

Canine osteosarcoma; 12 dogs

- Maximum tolerated dose ~2x of Quadramet® (2 mCi/kg vs 1 mCi/kg)
- Pain palliation; 7 dogs improved or stable indices
- Safety and efficacy achieved

College of Veterinary Medicine
University of Missouri

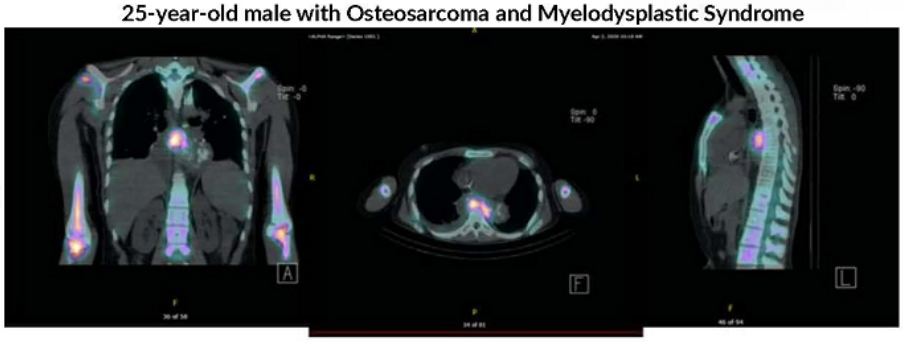
2020 Cleveland Clinic Study Indicates Early Safety Signals at High Dosages with CycloSam

QSAM Biosciences

FDA-Cleared Single Patient IND
Cleveland Clinic
March '20

Single high dose (32 mCi/kg; 10X Phase 1 max dose) administration of CycloSam® for bone marrow ablation prior to stem cell transplant on terminally ill patient

25-year-old male with Osteosarcoma and Myelodysplastic Syndrome



4-2-20 Two days after 153-Sm-DOTMP (32 mCi/kg): Fusion bone scan + SPECT CT images show osteosarcoma and skeleton uptake (but no lung and very little uptake in soft tissues).

Clinical Outcomes

- CycloSam® targeted bone; preferential uptake in tumors
- ~50% CycloSam® delivered to target
- ~40 GRAY Dose to Marrow
- No Dose Saturation
- Cleared major organs within hours
- Normal Kidney Function

Note: Stem cell transplant was performed but did not engraft; *Patient died five months subsequent of unrelated causes.*

Source: Peter Anderson, MD, unpublished data, IND 147858 Report, December 2020.

Initiated Phase 1 Bone Mets Trial: First Patient Results Show Safety and Early Efficacy Signals

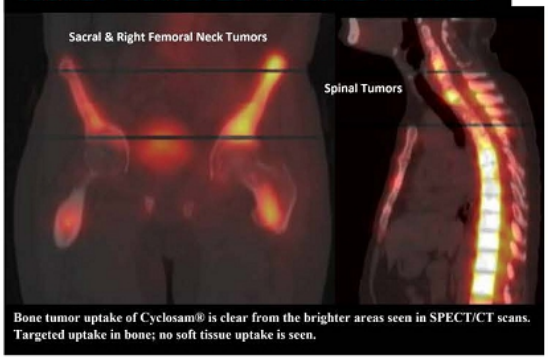
QSAM Biosciences

Age 61 male with prostatic adenocarcinoma cancer metastatic to bone given two 0.5mCi/kg doses of CycloSam® 7 days apart

Results

- Targeted uptake in the bone tumors
- Rapid elimination
- Favorable blood results
- Decreased tumor metabolic activity
- Significantly diminished pain
- No toxicities or drug-related adverse events

HIGHLY TARGETED TO BONE TUMORS



Bone tumor uptake of Cyclosam® is clear from the brighter areas seen in SPECT/CT scans. Targeted uptake in bone; no soft tissue uptake is seen.

* Early data on single patent; future results may not be similar.

SAFETY*

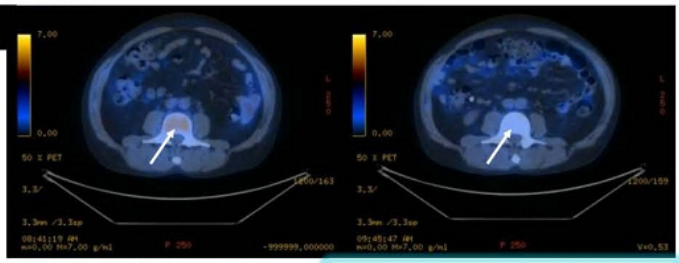
Blood Profile: Baseline and 42-day Complete Blood Counts (CBC) and Complete Metabolic Panels (CMP) were taken. CBCs indicate a slight expected drop in blood cell counts that are not clinically significant. No transfusions or stem cell recovery procedures were implemented for this subject. CMPs indicate no clinically significant changes in liver and kidney function tests. Select relevant CBC and CMP data are below.

Test	Baseline (Previous) 04/07/2022	42 Days Post (Previous) 06/02/2022	Units	Normal Range
WBC	6.3 (5.3)	4.9 (4.2)	x10*3/uL	3.7-12.1
RBC	4.0	3.6	x10*6/uL	4.5-6.1
HGB	10.5 (10.3)	9.5 (9.9)	g/dl	13.5-18.0
HCT	34.2 (33.5)	30.4 (31.2)	%	42.0-54.0
ANC	5.3 (4.0)	3.1 (2.9)	x10*3/uL	2.0-8.0
PLT	275.0 (262.0)	270.0 (211.0)	x10*3/uL	138.0-477.0

WBC=White Blood Cells, RBC=Red Blood Cells, HGB=Hemoglobin, HCT=Hematocrit, ANC=Absolute Neutrophil Count, PLT=Platelet Count

L3 Metabolic Activity Compared (PET/CT)

EFFICACY*

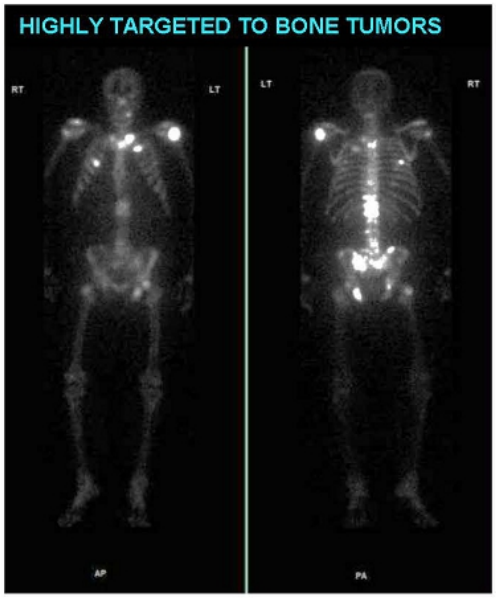


[04/18/2022] Metabolic Activity: 4.1

[05/31/2022 Post Dosing Metabolic Activity: 1.5] 63% DECREASE

Ongoing Phase 1 Bone Mets Trial: Promising Second Patient Results

QSAM Biosciences



- Results from SPECT/CT scans show that CycloSam® uptake in bone tumors is robust and visible; no soft tissue activity; rapid blood clearance
- Favorable blood results at day 38; WBC & platelets remained in normal range
- Patient experienced marked improvement in VAS pain score and quality of life (64 to 7 on a scale of 100 after 2nd dose; no longer cane-dependent or hospice bound)

SAFETY*

LAB TEST	Screening 8/5/2022	(Day1) 8/31/2022	(Day8) 9/7/2022	Day38 10/10/2022	EOT 11/9/2022	UNITS	RANGE
Hemoglobin	12.2	12.5	12.7	12.5	13.1	g/dl	13.5-18.0
Hematocrit	37.9	38.5	38.6	38.1	38.5	%	42.0-54.0
Red Blood Cell Count	3.9	3.9	4	3.93	4.18	x10*6/uL	4.5-6.1
White Blood Cell Count	**8.9**	**9.5**	**6.2**	**6**	**6.89**	**x10*3/uL**	**3.7-12.1**
Absolute Neutrophil Count	6.3	8.1	4.5	4.4	4.83	x10*3/uL	2.0-8.0
Platelet Count	**205**	**225**	**215**	**177**	**199**	**x10*3/uL**	**138.0-477.0**
BUN		14	22	13	17	mg/dL	8-27
Creatinine		0.75	0.67	0.85	0.71	mg/dL	0.57-1.00
AST/SGOT		21	28	29	25	IU/L	0-40
ALT/SGPT		20	22	39	19	IU/L	0-32
Alkaline Phosphatase (ALP)		187	185	150	178	IU/L	44-121
Total Bilirubin		0.2	0.2	0.2	0.2	mg/dL	0.0-1.2

* Early data on single patent; future results may vary

QSAM Biosciences

Investor Highlights

QSAM presents an attractively valued opportunity in **rapidly growing and deal-active** radiopharmaceutical sector

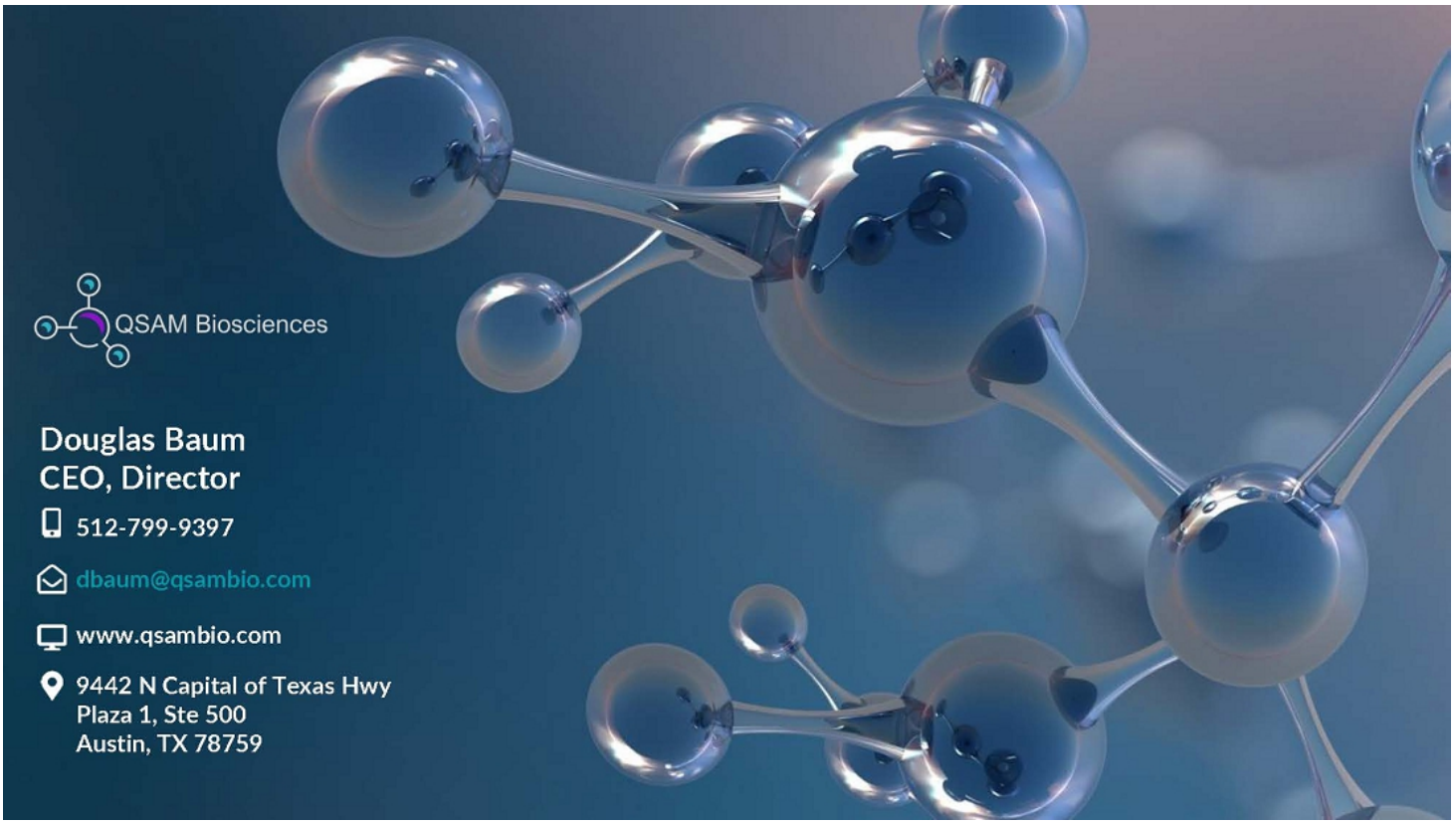
Experienced management with successful record of FDA approvals, big pharma/gov partnerships and M&A

Initial asset materially de-risked through patented improvements over FDA approved drug; with precedent for safety, efficacy

Potential indications include multiple large, underserved markets; Orphan and Rare Pediatric Designation

Well-defined and achievable Exit Opportunity within 24-30 months; Several nearer-term inflection points that can drive value

Forward looking statements – actual results may differ materially.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