

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: June 9, 2014
(Date of earliest event reported)

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

Delaware

(State or other jurisdiction
of incorporation)

333-119366

(Commission
File Number)

04-3321804

(IRS Employer
Identification Number)

**3301 Agriculture Drive
Madison, WI 53716**
(Address of principal executive offices)

(608) 441-8120
(Registrant's telephone number, including area code)

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))
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ITEM 5.03 AMENDMENTS TO ARTICLES OF INCORPORATION OR BYLAWS

Effective at the close of business on June 13, 2014, we amended our second amended and restated certificate of incorporation to effect a 1-for-20 reverse split of our common stock (the “Reverse Split”) and to reduce the number of authorized shares of our common stock to 20,000,000 from 150,000,000. Immediately following the effectiveness of the Reverse Split, there were approximately 2,869,739 shares of our common stock outstanding. Stockholders will receive a cash payment in lieu of any issuance of fractional shares. The number of shares of common stock issuable upon exercise or conversion of all outstanding options, warrants and convertible debt and the associated exercise or conversion prices will be adjusted accordingly for the Reverse Split.

At our annual meeting of stockholders held on May 22, 2014, our stockholders approved an amendment to our certificate of incorporation that would (1) effect a reverse split of our common stock at a ratio between 1:10 to 1:20 to be determined by the board of directors in its discretion and (2) if the reverse split is effected, decrease the number of shares of Common Stock that the Corporation is authorized to issue from 150,000,000 to the greater of (A) 20,000,000 and (B) the number of shares equal to three (3) times the sum of the number of all shares of our common stock outstanding and the number of shares of common stock issuable upon exercise or conversion of all outstanding options, warrants and convertible debt. Our stockholders further authorized the board of directors to determine the ratio at which the reverse split would be effected and the corresponding reduction in authorized shares of common stock by filing an appropriate amendment to our certificate of incorporation. Our board of directors authorized the ratio of the Reverse Split and corresponding reduction in authorized shares on June 6, 2014.

A copy of the amendment to our certificate of incorporation is attached as Exhibit 3.1 and is incorporated by reference herein.

ITEM 7.01 REGULATION FD DISCLOSURE

A copy of the press release issued by us on June 13, 2014 announcing the Reverse Split is furnished as Exhibit 99.1 and is incorporated by reference herein.

ITEM 8.01 OTHER ITEMS

On June 9, 2014 and June 10, 2014 presentations relating to our technology were made at the 2014 Annual Meeting of the Society of Nuclear Medicine. The presentations are attached as Exhibit 99.2 and 99.3 and are incorporated by reference herein.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Number	Title
3.1	Certificate of Amendment to the Second Amended and Restated Articles of Incorporation of Collectar Biosciences, Inc.
99.1	Press Release dated June 13, 2014 entitled “Collectar Biosciences Announces 1-for-20 Reverse Stock Split and Reduction in Authorized Shares of Common Stock”
99.2	Presentation entitled “A Phase 1 Study of 131I-CLR1404 in Patients with Relapsed or Refractory Advanced Solid Tumors; Dosimetry, Biodistribution, Pharmacokinetics and Safety”
99.3	Presentation entitled “Comparison of MRI and PET Tumor Volumes with 124I-CLR1404 PET/CT in Primary and Metastatic Brain Tumors”

SIGNATURE

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.

Dated: June 13, 2014

CELLECTAR BIOSCIENCES, INC.

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Vice President and Chief Financial Officer

EXHIBIT INDEX

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**CERTIFICATE OF AMENDMENT
TO
THE SECOND AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
CELLECTAR BIOSCIENCES, INC.**

CELLECTAR BIOSCIENCES, INC. (the “Corporation”), a corporation organized and existing under of the General Corporation Law of the State of Delaware, does hereby certify:

FIRST: The name of the Corporation is Cellectar Biosciences, Inc.

SECOND: The Second Amended and Restated Certificate of Incorporation of the Corporation is hereby amended as follows.

1. By inserting the following paragraphs in Article FOURTH thereof immediately following the first paragraph of said Article FOURTH:

“Upon the effectiveness of the amendment to the Amended and Restated Certificate of Incorporation adding this paragraph thereto (the “Effective Time”), each share of Common Stock, par value \$0.00001 per share issued and outstanding immediately prior to the Effective Time (the “Original Common Stock”), shall be reclassified into 1/20 of a share of Common Stock, such Common Stock to have the rights and powers set forth in the Certificate of Incorporation and under the General Corporation Law of the State of Delaware (the “Reclassification”). All shares of Common Stock issued to any holder of Original Common Stock as a result of the Reclassification shall be aggregated for the purpose of determining the number of shares of Common Stock to which such holder shall be entitled, and no fractional shares shall be issued in connection with the Reclassification.

Any stockholder who would otherwise be entitled to receive a fractional share of Common Stock as a result of the Reclassification shall receive in lieu thereof cash in an amount equal to such fraction multiplied by the fair market value of one share of Common Stock, based on the average of the high and low bid prices of the Common Stock as quoted on the Over-the-Counter Bulletin Board on the last trading day immediately preceding the Effective Time. No cash in lieu of any fractional share shall be paid to any stockholder until such stockholder shall have surrendered for transfer or otherwise accounted to the Corporation for the outstanding stock certificates entitling such stockholder to such cash.

At and after the Effective Time, outstanding certificates that prior thereto represented shares of Original Common Stock shall be deemed for all purposes to evidence ownership of and to represent that number of shares of Common Stock into which the shares previously represented by such certificates have been reclassified as herein provided (and the right to receive cash in lieu of any fraction of a share as provided herein). Until any such outstanding stock certificates have been surrendered for transfer or otherwise accounted for to the Corporation, the registered owner thereof on the books and records of the Corporation shall have and be entitled to exercise any voting and other rights with respect to, and receive any dividend and other distributions upon, the shares of Common Stock issued in respect of the Original Common Stock formerly evidenced by such certificates.”; and

2. By amending and ratifying in its entirety the first paragraph of Article FOURTH as follows:

“Fourth. The aggregate number of shares of stock that the Corporation shall have authority to issue is twenty million and seven thousand (20,007,000), of which twenty million (20,000,000) shares shall be designated “Common Stock” and seven thousand (7,000) shares shall be designated “Preferred Stock.” Shares of Common Stock and Preferred Stock shall have a par value of \$0.00001 per share.”

THIRD: The foregoing amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

FOURTH: The foregoing amendment shall be effective at 5:00 pm eastern time on June 13, 2014.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation to be signed by Simon Pedder, its President and Chief Executive Officer, thereto duly authorized, this 10th day of June, 2014.

CELLECTAR BIOSCIENCES, INC.

By: /s/ Simon Pedder

Simon Pedder

President and Chief Executive Officer



**Collectar Biosciences Announces 1-for-20 Reverse Stock Split and Reduction
in Authorized Shares of Common Stock**

MADISON, Wis., June 13, 2014, – Collectar Biosciences, Inc. (OTCQX: CLRB), announced a 1-for-20 reverse stock split of its common stock, effective at the close of business today, as a first step in a planned listing of its common stock on the NASDAQ Capital Market.

Shares of Collectar's common stock will trade on a post-split basis beginning on June 16, 2014. The Company's ticker symbol will remain unchanged, although a "D" will be placed on the ticker symbol, CLRB, for 20 business days to alert the public to the Reverse Split. The new CUSIP number for Collectar's common stock post-reverse stock split will be 15117F 203.

At the effective time of the reverse stock split, every 20 shares of Collectar's issued and outstanding common stock will automatically be combined into 1 issued and outstanding share of common stock without any change in the par value of the shares. This will reduce the number of outstanding common shares of Collectar from approximately 57 million to approximately 2.8 million. In conjunction with the reverse stock split, Collectar will decrease the number of its authorized shares of common stock from 150,000,000 to 20,000,000. Stockholders approved the reverse split and the reduction in authorized shares at the 2014 Collectar Annual Meeting held on May 22, 2014. Additional information can be found in a Form 8-K to be filed with the Securities and Exchange Commission.

"We believe this reverse split will make an investment in Collectar both viable and more appealing to a broader institutional investment community," commented Dr. Simon Pedder, president and chief executive officer of Collectar. "Coupled with a successful capital raise, the next prerequisite, and planned NASDAQ listing, we should be able to meaningfully increase stockholder value as we execute our clinical programs and advance our pipeline of promising cancer-targeting imaging and therapeutic technology."

Proportionate voting rights and other rights of common stockholders will not be affected by the reverse stock split, other than as a result of the cashing out of fractional shares. Stockholders who would otherwise hold a fractional share of common stock will receive a cash payment in lieu of a fractional share. Please direct any questions you might have regarding payments for fractional shares to your broker or our transfer agent, American Stock Transfer & Trust Company, by calling (718) 921-8317.

About Collectar Biosciences, Inc.

Collectar Biosciences is developing agents to detect, treat and monitor a broad spectrum of cancers. Using a novel phospholipid ether analog (PLE) platform technology as a targeted delivery and retention vehicle, Collectar's compounds are designed to be selectively taken up and retained in cancer cells including cancer stem cells. With the ability to attach both imaging and therapeutic agents to its proprietary delivery platform, Collectar has developed a portfolio of product candidates engineered to leverage the unique characteristics of cancer cells to "find, treat and follow" malignancies in a highly selective way. I-124-CLR1404 is a small-molecule, broad-spectrum, cancer-targeted PET imaging agent currently being evaluated in a Phase II glioblastoma imaging trial. Additionally, multiple investigator-sponsored Phase I/II clinical trials are ongoing across 11 solid tumor indications. I-131-CLR1404 is a small-molecule, broad-spectrum, cancer-targeted molecular radiotherapeutic that delivers cytotoxic radiation directly and selectively to cancer cells including cancer stem cells. A Phase Ib dose-escalation trial of I-131-CLR1404 in patients with advanced solid tumors was completed in the first quarter of 2014 and results presented at the American Society of Clinical Oncology (ASCO) 2014 Annual Meeting. CLR1502 is a preclinical, cancer-targeted, non-radioactive optical imaging agent for intraoperative tumor margin illumination and non-invasive tumor imaging. For additional information please visit www.collectar.com

INVESTOR CONTACT

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This news release contains forward-looking statements. You can identify these statements by our use of words such as "may," "expect," "believe," "anticipate," "intend," "could," "estimate," "continue," "plans," or their negatives or cognates. These statements are only estimates and predictions and are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to raise additional capital, uncertainties related to the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, the completion of clinical trials, the FDA review process and other government regulation, our pharmaceutical collaborators' ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement. A complete description of risks and uncertainties related to our business is contained in our periodic reports filed with the Securities and Exchange Commission including our Form 10-K for the year ended December 31, 2013. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

Joseph J Grudzinski^{1,2}, Benjamin Titz^{1,2}, Kevin Kozak¹, William Clarke¹, Ernest Allen¹, LisaAnn Trembath¹, Michael Stabin⁴, John Marshall⁵, Steve Y. Cho⁶, Terence Z. Wong⁷, Joanne Mortimer⁸, Jamey P Weichert^{1,3}

¹Cellular Biosciences, Inc. ²Department of Medical Physics, University of Wisconsin SMPH ³Department of Radiology, University of Wisconsin ⁴Vanderbilt University ⁵Georgetown University ⁶Johns Hopkins Hospital ⁷Duke University Medical Center ⁸City of Hope

¹²⁵I-R10434 is a small molecule that combines a tumour targeting moiety with a therapeutic radionuclide. The primary aim of this study was to determine the administered radioactivity vs. the delivery of radioactivity to the bone marrow. The secondary aims of the study were to determine the distribution of radioactivity (PNC) and the profile of the radioactivity in the marrow. Mice were injected with 100 µCi of ¹²⁵I-R10434 and sacrificed at 1, 2, 4, 8, 16, 32, 64, 128, 256, 512, 1024, 2048, 4096, 8192, 16384, 32768, 65536, 131072, 262144, 524288, 1048576, 2097152, 4194304, 8388608, 16777216, 33554432, 67108864, 134217728, 268435456, 536870912, 1073741824, 2147483648, 4294967296, 8589934592, 17179869184, 34359738368, 68719476736, 137438953472, 274877906944, 549755813888, 1099511627776, 2199023255552, 4398046511104, 8796093022208, 17592186044416, 35184372088832, 70368744177664, 140737488355328, 281474976710656, 562949953421312, 1125899906842624, 2251799813685248, 4503599627370496, 9007199254740992, 18014398509481984, 36028797018963968, 72057594037927936, 144115188075855872, 288230376151711744, 576460752303423488, 1152921504606846976, 2305843009213693952, 4611686018427387904, 9223372036854775808, 18446744073709551616, 36893488147419103232, 73786976294838206464, 147573952589676412896, 295147905179352825792, 590295810358705651584, 1180591620717411303168, 2361183241434822606336, 4722366482869645212672, 9444732965739290425344, 18889465931478580850688, 37778931862957161701376, 75557863725914323402752, 151115727451828646805504, 302231454903657293611008, 604462909807314587222016, 1208925819614629174444032, 2417851639229258348888064, 4835703278458516697776128, 9671406556917033395552256, 19342813113834066791104512, 38685626227668133582209024, 77371252455336267164418048, 154742504910672534328836096, 309485009821345068657672192, 618970019642690137315344384, 1237940039285380274630688768, 2475880078570760549261377536, 4951760157141521098522755072, 9903520314283042197045510144, 19807040628566084394091020288, 39614081257132168788182040576, 79228162514264337576364081152, 158456325028528675152728162304, 316912650057057350305456324608, 633825300114114700610912649216, 1267650600228229401221825298432, 2535301200456458802443650596864, 5070602400912917604887301193728, 10141204801825835209774602387456, 20282409603651670419549204774912, 40564819207303340839098409549824, 81129638414606681678196819099648, 162259276829213363376393638199296, 324518553658426726752787276398592, 649037107316853453505574552797184, 1298074214633706907011149105594368, 2596148429267413814022298211188736, 5192296858534827628044596422377472, 10384593717069655256089192844754944, 20769187434139310512178385689509888, 41538374868278621024356771379019776, 83076749736557242048713542758039552, 166153499473114484097427085516079104, 332306998946228968194854171032158208, 664613997892457936389708342064316416, 1329227995784915872779416684128632832, 2658455991569831745558833368257265664, 5316911983139663491117666736514531328, 10633823966279326982235333473029062656, 21267647932558653964470666946058125312, 42535295865117307928941333892116250624, 85070591730234615857882667784232501248, 170141183460469231715765335568465002496, 340282366920938463431530671136930004992, 680564733841876926863061342273860009984, 1361129467683753853726122684547720019968, 2722258935367507707452245369095440039936, 5444517870735015414904490738190880079872, 10889035741470030829808981476381760159744, 21778071482940061659617962952763520319488, 43556142965880123319235925905527040638976, 87112285931760246638471851811054081267776, 174224571863520493276943703622108165355536, 348449143727040986553887407244216330711072, 696898287454081973107774814488432661422144, 1393796574908163946215549628976865322844288, 2787593149816327892431099257953730645688576, 5575186299632655784862198515907461291377152, 1115037259926531156972439703181492258275424, 2230074519853062313944879406362984516550848, 446014903970612462788975881272596903310176, 892029807941224925577951762545193806620352, 1784059615882449851155903525090387613240704, 3568119231764899702311807050180775226481408, 7136238463529799404623614100361550452962816, 14272476927059598809247228200723100905925632, 28544953854119197618494456401446201811851264, 5708990770823839523698891280289240362370256, 11417981541647679047397782560578480724740512, 228359630832953580947955651211569614494801024, 45671926166590716

Timeline of the study protocol:

- 2 weeks: Baseline
- Day 1: Treatment
- Day 11: Deconvolution calculation
- Day 10: OP254L
- Day 10: OP254L
- Day 12: End of study

The duration of the study is indicated by a double-headed arrow from day 1 to day 12.

Figure 1. Flowchart describing the clinical study.

Dosimetry and Radiologic Biodistribution Analysis. Total urine was collected for radiologic biodistribution analysis for the first 14 days of the study. Whole body planar imaging was performed at the following time points for assessment of total body and organ radiation dosimetry: 15–30 minutes, 4–6 hours, 18–24 hours, 48–6 hours, 72–6 hours, 144–6 hours, and Day 14–1 oral infusion.

Biodistribution data were analyzed using the Organ Level Internal Dose Assessment (OLINDA) methodology to produce time-activity curves and generate organ specific radiation absorbed doses from a 10 mCi injection of ^{211}Cl -CLIR404. These data, along with total urine collection for up to 14 days, were used to extrapolate and predict organ specific and total body radiation absorbed doses from therapeutic injections of ^{211}Cl -CLIR404.

Pharmacokinetics: A pharmacokinetic assessment of the plasma concentration of the parent compound (^{14}C)-CJRM54 was performed using a validated HPLC method with MS/MS detection (LLOQ 2.00 ng/mL).

Analyses of plasma [^{14}C]CURI434 CURI434 concentration-time data were conducted using non-compartmental methods and the pharmacokinetics of CURI434 were assessed by determining maximum plasma concentration (C_{max}), time to C_{max} (T_{max}), area under the concentration-time curve from 0 to 144 hours ($\text{AUC}(0-144\text{h})$), area under the concentration curve from time 0 to time 1 is the time of last quantifiable concentration ($t = 1028\text{h}$) ($\text{AUC}(0-t)$), plasma half-life ($t_{1/2}$), effective plasma half-life ($t_{1/2\text{eff}}$) and apparent terminal phase rate constant (λ_{z}), clearance (CL), volume of distribution (V_d), and volume of distribution at steady-state (V_{ss}).

Safety. Safety was assessed by adverse event (AE) monitoring, clinical laboratory tests (hematology, chemistry, lipids, and urinalysis), electrocardiogram (ECGs), vital signs including temperature and SaO₂, physical exams, determination of ECG performance status, serum pregnancy test for females of child-bearing potential, medical history and medication review.

Table 1: Author information. Details about the authors involved in the study.

Table 1. Patient characteristics and the type of patient care services received (N = 20)					
Age	Gender	Age Group	Primary Care	Secondary Care	Specialty Care
20	Male	18-24	Primary Care	Secondary Care	Specialty Care
21	Female	25-34	Primary Care	Secondary Care	Specialty Care
22	Male	35-44	Primary Care	Secondary Care	Specialty Care
23	Female	45-54	Primary Care	Secondary Care	Specialty Care
24	Male	55-64	Primary Care	Secondary Care	Specialty Care
25	Female	65-74	Primary Care	Secondary Care	Specialty Care
26	Male	75-84	Primary Care	Secondary Care	Specialty Care
27	Female	85-94	Primary Care	Secondary Care	Specialty Care
28	Male	95-104	Primary Care	Secondary Care	Specialty Care
29	Female	105-114	Primary Care	Secondary Care	Specialty Care
30	Male	115-124	Primary Care	Secondary Care	Specialty Care
31	Female	125-134	Primary Care	Secondary Care	Specialty Care
32	Male	135-144	Primary Care	Secondary Care	Specialty Care
33	Female	145-154	Primary Care	Secondary Care	Specialty Care
34	Male	155-164	Primary Care	Secondary Care	Specialty Care
35	Female	165-174	Primary Care	Secondary Care	Specialty Care
36	Male	175-184	Primary Care	Secondary Care	Specialty Care
37	Female	185-194	Primary Care	Secondary Care	Specialty Care
38	Male	195-204	Primary Care	Secondary Care	Specialty Care
39	Female	205-214	Primary Care	Secondary Care	Specialty Care
40	Male	215-224	Primary Care	Secondary Care	Specialty Care

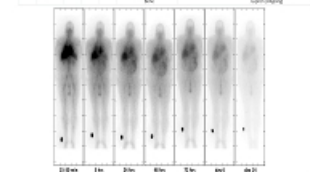


Figure 2: Whole body conjugate-view planar images for patient 301. Images are shown for 15-30 minutes, 4, 24, 48, 72 hours, 6 and 14 days post injection, respectively. Because the agent is metabolized in the hepatobiliary system, there is evidence of ^{125}I -CUR404 within the liver and intestines at relatively late time points.

Table 2 Summary of the desimetry results. Statistical summary of the eight parent desimetry variables

	average	stddev	min	max	cv%
Acidic	15.000	1.5624	9.0000	18.750	10.4%
Alkaline	15.000	1.5745	9.0000	18.750	10.5%
Benign	15.000	1.5800	9.0000	18.750	10.5%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000	18.750	10.4%
Neutral	15.000	1.5625	9.0000	18.750	10.4%
Acidic	15.000	1.5625	9.0000	18.750	10.4%
Alkaline	15.000	1.5625	9.0000	18.750	10.4%
Benign	15.000	1.5625	9.0000		

Table 3. Summary of results from the chemopreventive analysis

Subject Number	τ_{obs} (days)	ΔK_{obs} (mag)	ΔK_{c} (mag/mag)	$\Delta K_{\text{c}} - \Delta K_{\text{obs}}$ (mag/mag)	$\Delta K_{\text{c}} - \Delta K_{\text{obs}}$ (mag)	τ_{c} (days)	$\tau_{\text{c,fit}}$ (days)	Q (mag)	W (mag)
Mean	70.2	6.832	1430	15753	160000	802	209	0.014	0.8
Min	64.5	6.75	1415	15650	159000	790	204	0.005	0.7
Max	74.8	6.92	1445	15850	161000	810	214	0.024	0.9
Median	70.5	6.798	1431	15717	160000	804	206	0.016	0.8
Min	65.5	6.427	1409	15598	159004	794	203	0.015	0.7
Max	75	7.2	1471	16133	163333	817	215	0.031	0.9

Figure 1 displays PET/CT images for two patients, Patient 001 and Patient 002. The images are arranged in a 2x3 grid. The top row shows Patient 001, and the bottom row shows Patient 002. For each patient, three views are provided: axial (left), coronal (middle), and sagittal (right). Each view consists of a CT scan (top) and a PET/CT fusion image (bottom). The PET/CT fusion images show the PET signal overlaid on the CT scan, with color-coded intensity scales indicating the PET signal. The PET signal is highest in the central regions of the chest and pelvis, indicating the presence of the tumor.

Figure 2: Images of two infants with lesions operable to SPECT/CT study.

- As administered activity of approximately 740 MBq (20 mCi) is predicted to deliver 40 cGy to the tumor.
- Single doses of 10 mCi of ^{125}I -CA404 were well tolerated when administered to subjects with advanced cancers. There were no SAEs reported and all AEs were considered minimal, manageable and not dose limiting.
- After an intravenous administration of 10 mCi of ^{125}I -CA404 (0.3 mg total mass dose) CL1844 declined in a bi-exponential manner with a mean $t_{1/2}$ value of 822 hours.
- Mean CL_{1844} and AUC_{0-24} values were 72.2 mL/min and 16753 $\text{ng}\cdot\text{h/mL}$, respectively.



Collecta Biosciences

Study funded by Cellerar Biosciences, Inc.

Comparison of MRI and PET Tumor Volumes with ^{124}I - CLR1404 PET/CT in Primary and Metastatic Brain Tumors

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Disclosures

- ▣ **NIH/NCI: 1 R01 CA158800** (PI: Hall/Weichert)
 - ▣ UW ICTR from **NIH/NCATS: UL1TR000427** (PI: Hall)
 - ▣ UW Carbone Cancer Center from **NIH/NCI: P30CA014520** (PI: Hall)

 - ▣ Lance Hall -- No financial COI
 - ▣ Physician sponsor of IND for ¹²⁴I-CLR1404
 - ▣ Jamey Weichert – inventor of CLR1404 and founding member of Cellerar Biosciences, Inc
 - ▣ Benjamin Titz & Joseph Grudzinski – employees of Cellerar Biosciences, Inc
-

Brain Tumor Imaging - Limitations

- ▣ Incomplete delineation of tumor infiltration
 - Affects surgical resection & XRT planning & survival
 - ▣ Non-specificity for tumor vs necrosis or edema
 - Biopsy site planning & resection of eloquent brain
 - ▣ Differentiating tumor recurrence from pseudoprogression (PP)
 - Huge problem w/ Temozolomide & newer agents
 - ▣ Predict tumor response to Tx
 - Prospective response & individual tumor dosimetry
-

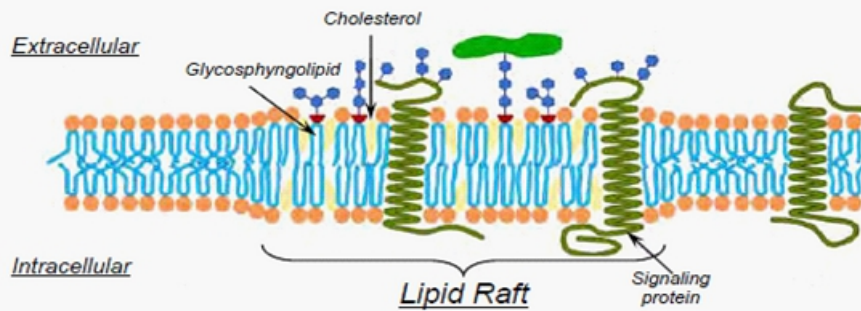
CLR1404 (aka “NM404”) Background

- ▣ Phospholipid ether (PLE) analog
- ▣ Enters malignant cells via membrane lipid rafts
 - Over expressed in malignant cells (6 – 10x)
- ▣ Tumor specific uptake & prolonged retention in >50 preclinical models
 - Including gliomas
- ▣ Isoteric iodine substitution
 - ^{124}I - for molecular/PET imaging
 - ^{131}I - for therapy
 - Optical imaging agents also being developed



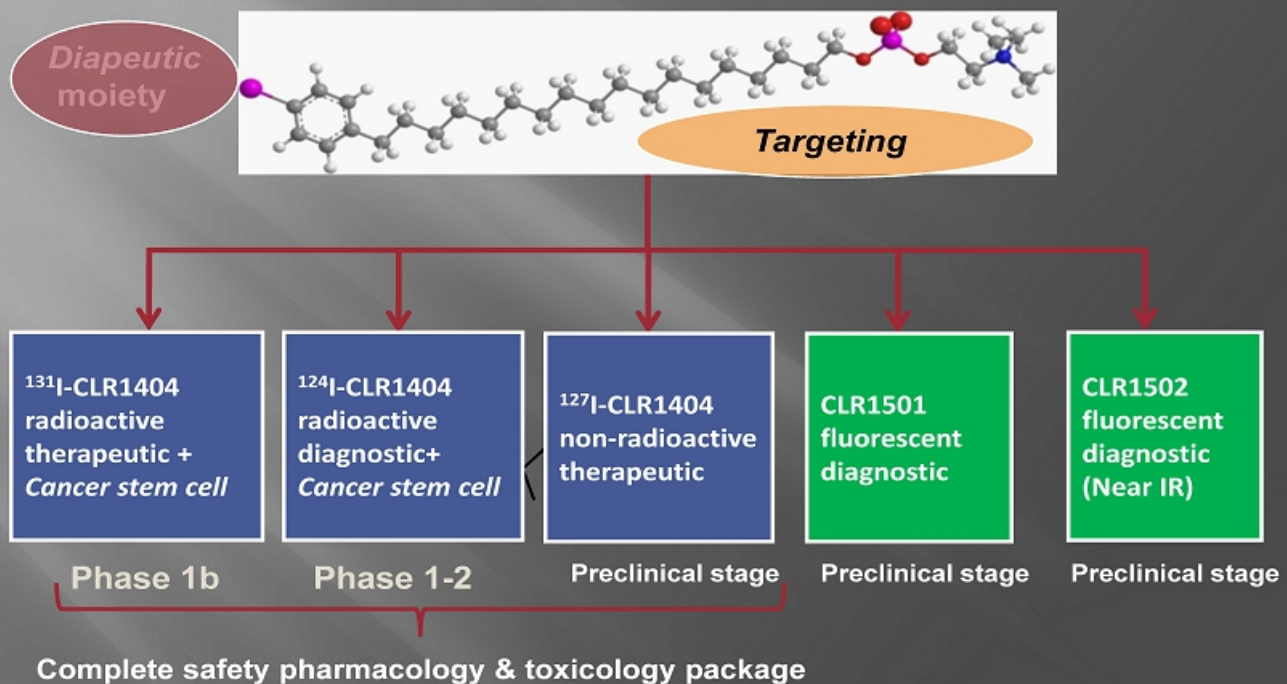
“Diapet”

Lipid Rafts

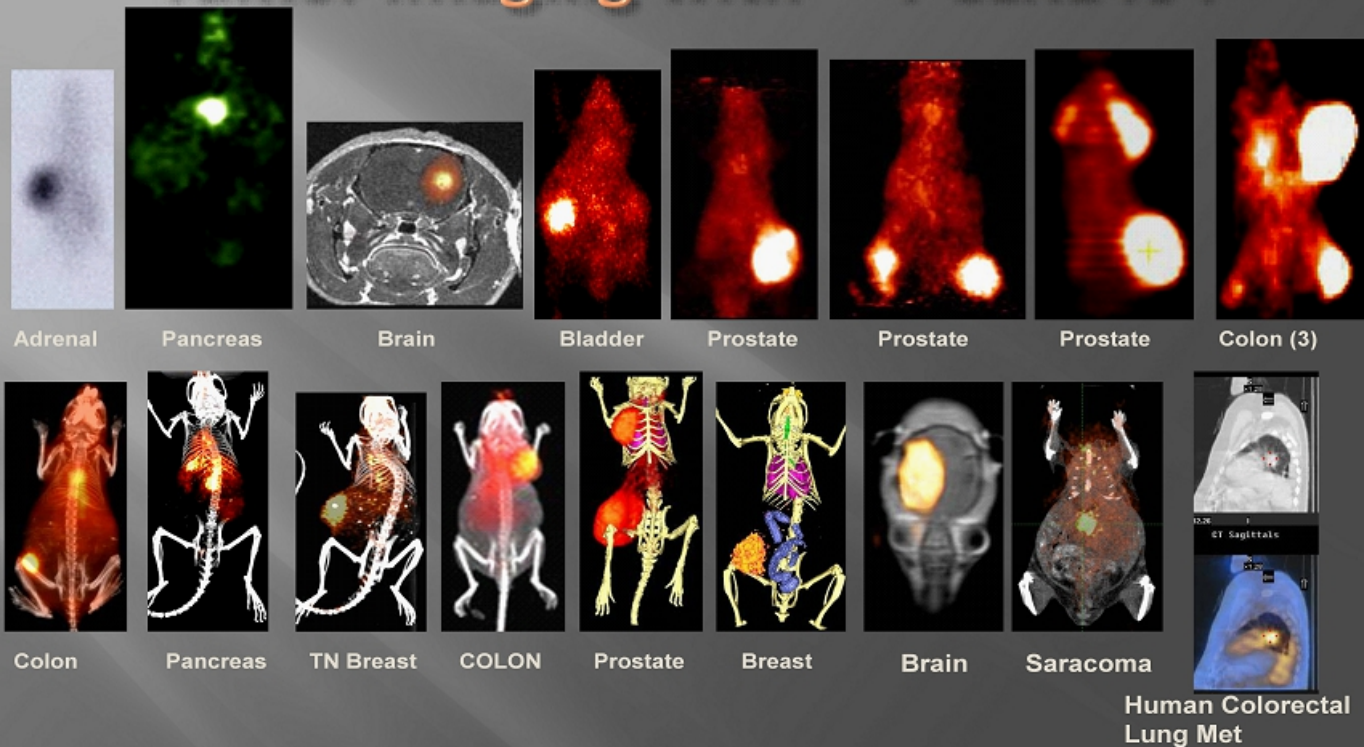


- ◆ Lipid rafts are specialized microdomains of plasma membrane that are enriched in cholesterol and glycosphingolipids
- ◆ Lipid rafts serve as molecular platforms that spatially organize molecules for specific signaling pathways including those involved in regulation of apoptosis and cell proliferation (e.g. growth factor receptors, Akt, TNF receptors)

Diapeutic Phospholipid Ether Analogs



Tumor Imaging with ^{124}I -CLR1404



Primary+Mets in 55/57 xenograft and spontaneous models

Objectives

- ▣ Describe first successful use of ^{124}I -CLR1404 in humans with brain tumors
 - Avidity in brain tumors
 - SUV and Tumor to Background Ratios
 - Compare PET and MRI
 - ▣ Tumor volumes
 - ▣ Concordant and discordant tumor regions
-

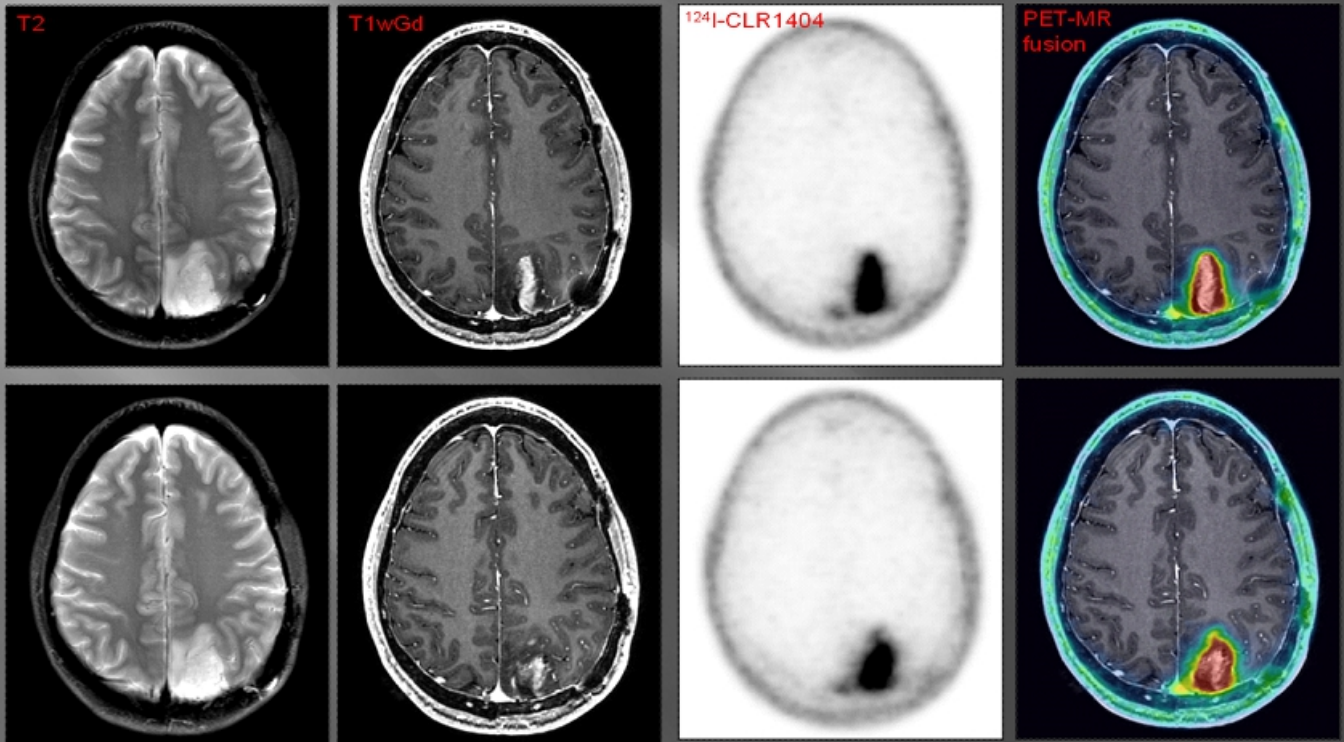
Methods

- ▣ 16 pts with brain tumors
 - 1 new dx (WHO Gr IV)
 - 11 previously tx'd gliomas (WHO Gr II – IV)
 - 3 previously tx'd metastases
 - 1 previously tx'd medulloblastoma
 - ▣ 2 or 5 mCi (74 or 185 MBq) ^{124}I -CLR1404 iv
 - ▣ PET/CT at 6-, 24-, and 48-hours after injection
 - 2D, list-mode, 90 minutes per scan
 - ▣ Qualitative review of PET tumor uptake & MRI signal
 - ▣ PET & MRI tumor volumes and SUVs and tumor-background ratios (T:B)
 - Amira segmentation to define tumor volumes
 - “mirror-image” tumor ROI placed in contralateral normal hemisphere
 - ▣ 14 pts followed to surgery or w/ serial MRI $\geq$ 6 months
-

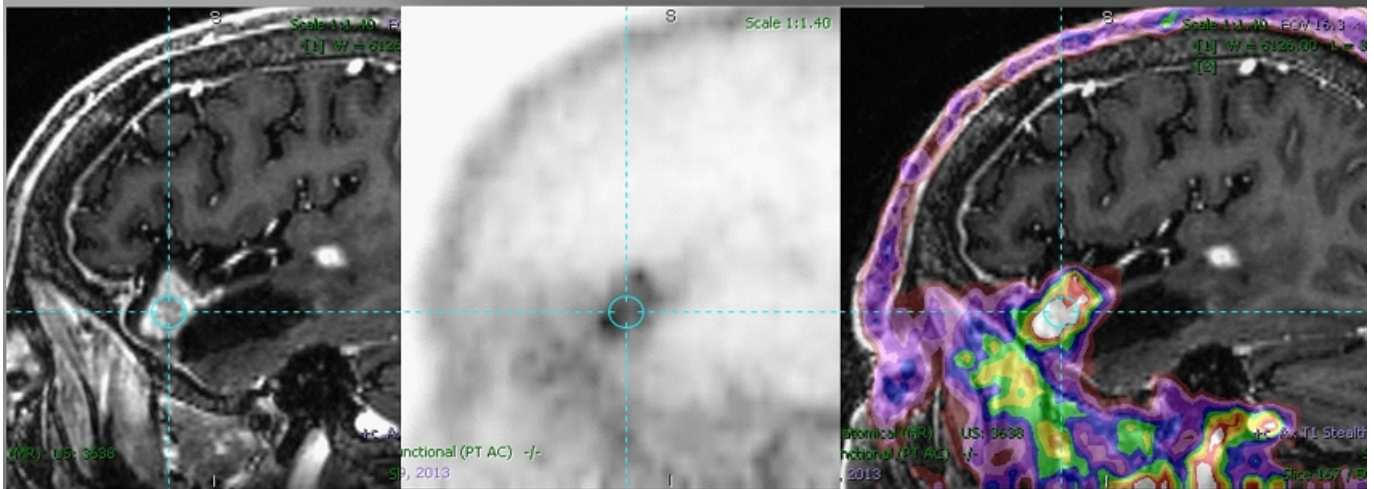
Results

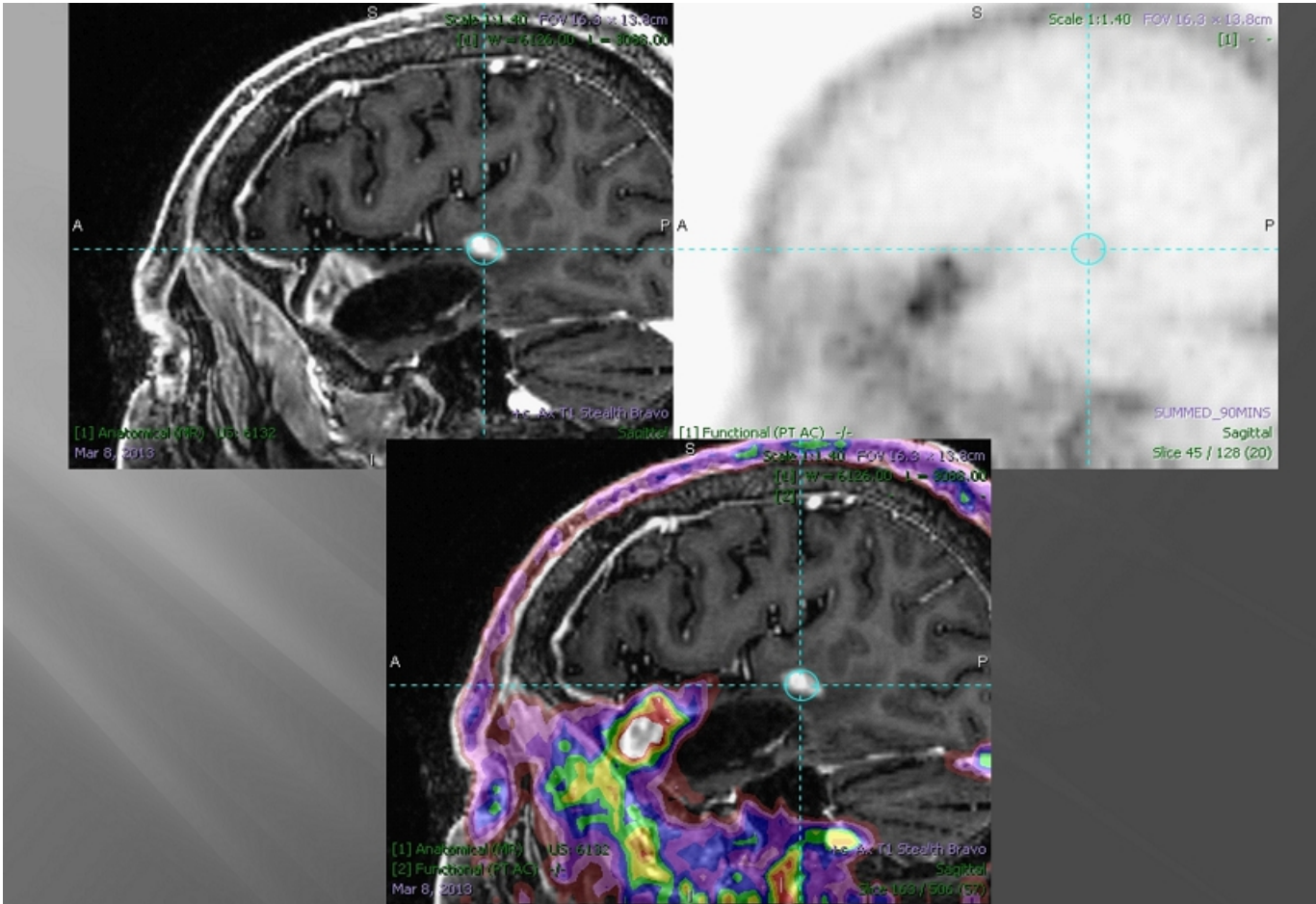
- ▣ No uptake in normal brain
 - ▣ Uptake in major vascular structures
 - Not in all areas of breakdown of BBB
 - ▣ 12/16 pts had avid tumor uptake
 - 4 pts w/ recurrence vs PP had no uptake
 - Tumor uptake typically increases over time
 - ▣ Both areas of concordant & discordant PET uptake and MRI enhancement
-

WHO Grade III Glioma (recurrent vs PP)

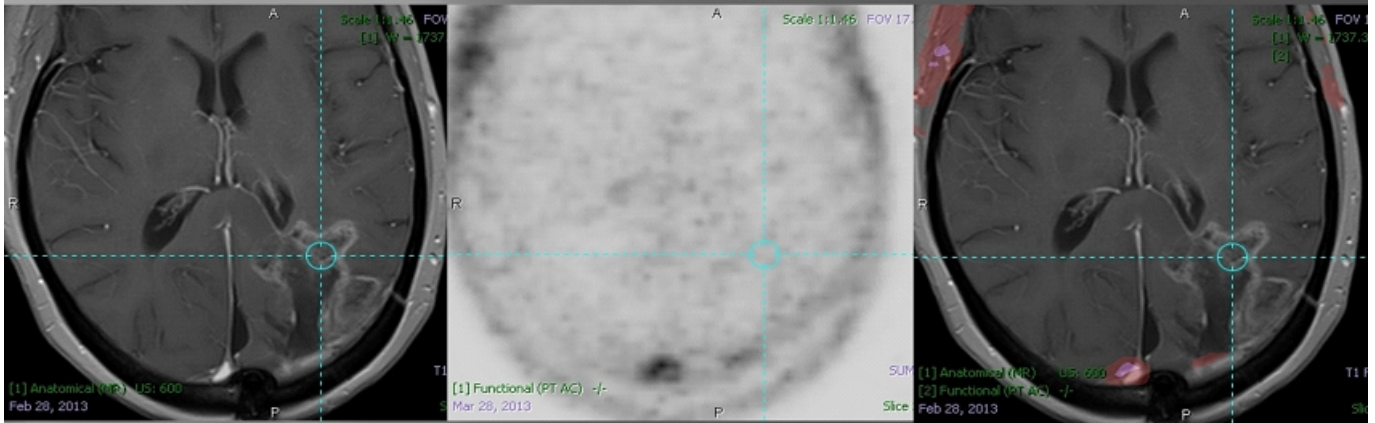


WHO Gr IV Glioma (recurrent vs PP)

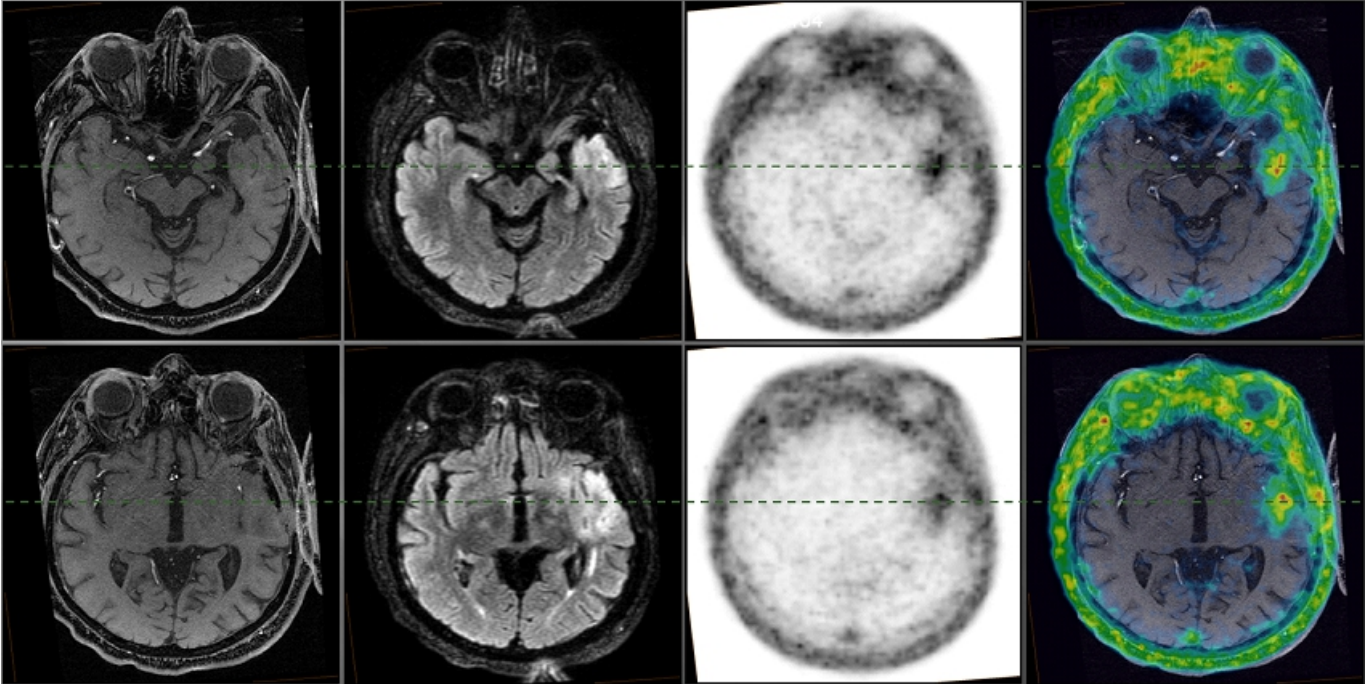




WHO Gr IV Glioma (Recurrent vs PP)

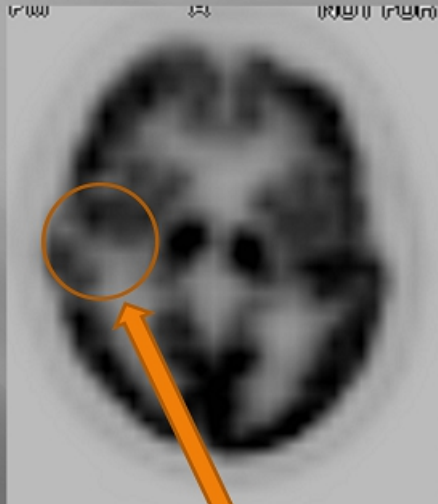


WHO Gr II Glioma (Recurrent vs PP)



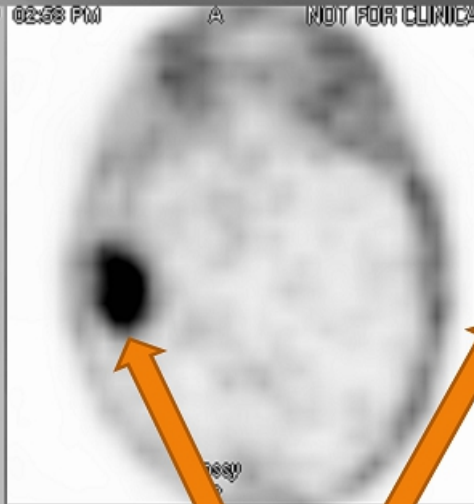
NSCLC w/ unsuspected Brain Mets

FDG-PET



Brain met not seen on FDG PET

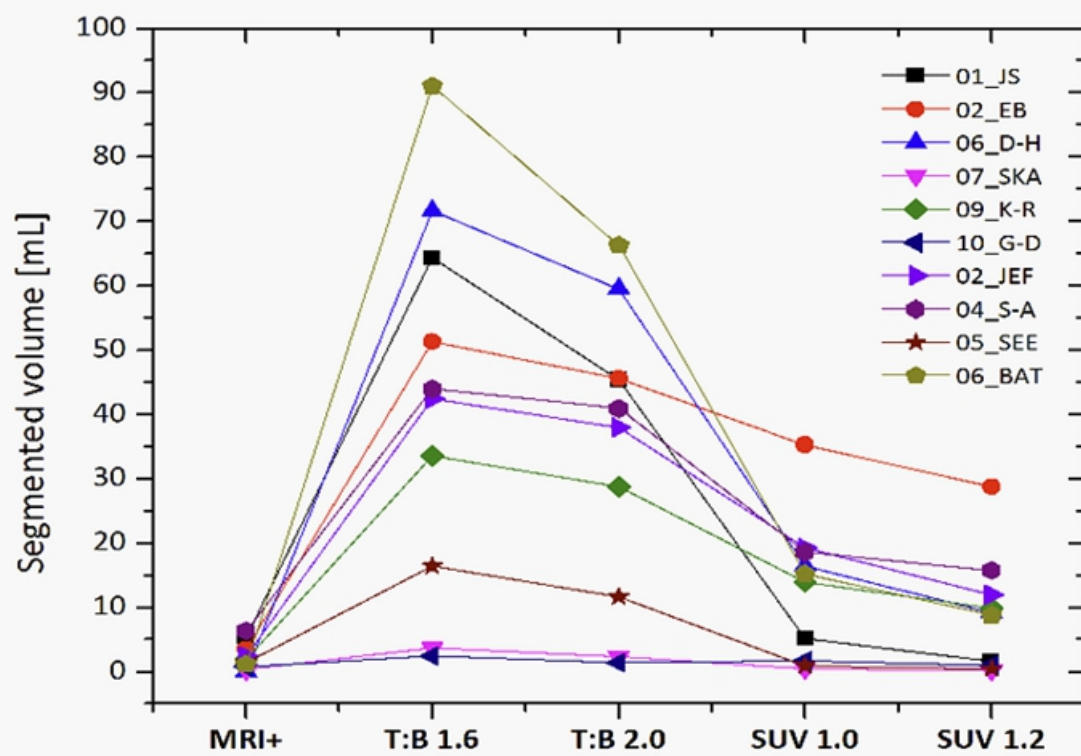
124I-NM404 PET

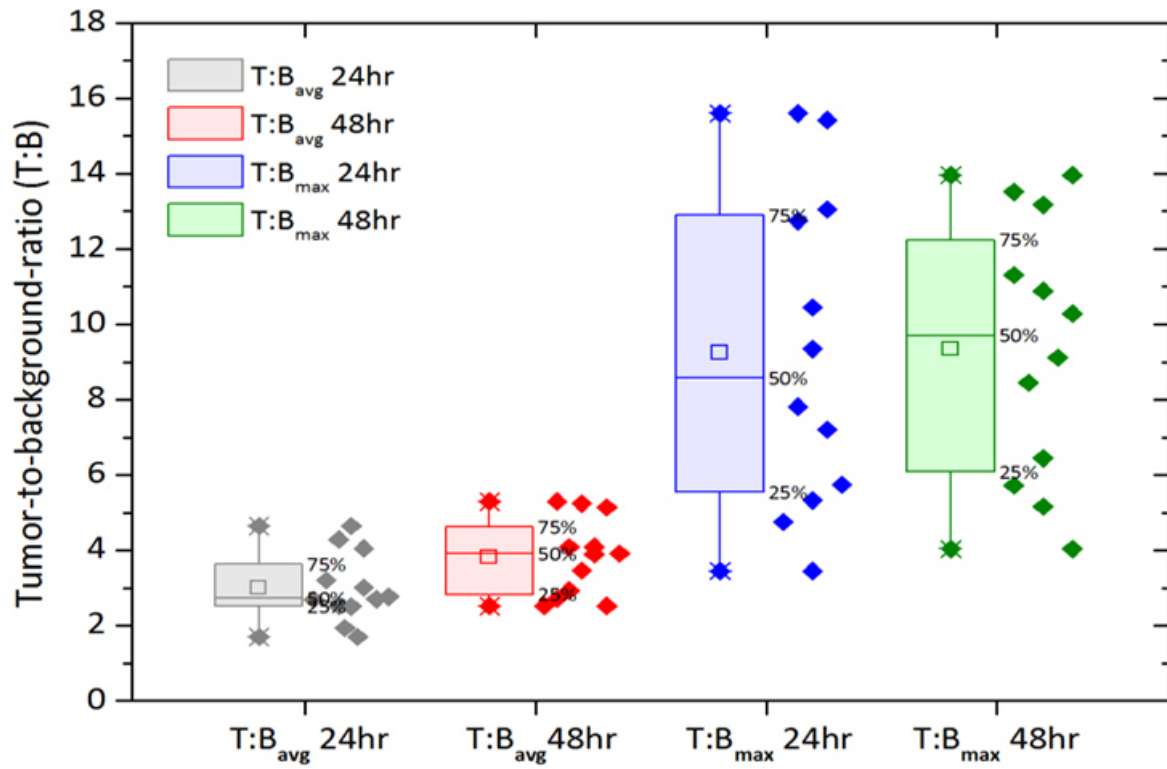


Brain met clearly seen on NM404 PET

Contrast MRI







Conclusion

- ▣ ^{124}I -CLR1404 successfully images primary and metastatic brain tumors in humans
 - ▣ PET tumor volumes larger than MRI + Gad
 - ▣ There is significant tumor to background uptake and prolonged retention
 - ▣ Additional functional tumor info provided
 - ▣ Potential for use as its own biomarker for targeted molecular radiotherapy
-

THANK YOU!



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