

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): September 29, 2026

ALZAMEND NEURO, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

001-40483

(Commission File Number)

81-1822909

(I.R.S. Employer Identification No.)

3480 Peachtree Road NE, Second Floor, Suite 103, Atlanta, GA 30326

(Address of principal executive offices) (Zip Code)

(844) 722-6333

(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:

- ☐

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
Common Stock, \$0.0001 par value	ALZN	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 Disclosure.

On September 29, 2026, Dr. Ovidiu C. Andronesi, principal investigator on Alzamend Neuro, Inc.’s Phase 1/2A Clinical Trial, Director of Multinuclear MRI, Martinos Center for Biomedical Imaging, Department of Radiology, Massachusetts General Hospital, and Associate Professor of Radiology at Harvard Medical School, will presented at the International Society for MR Radiographers & Technologists (ISMRT) Conference. A copy of the presentation, which is furnished herewith as **Exhibit 99.1**, is incorporated by reference herein.

In accordance with General Instruction B.2 of Form 8-K, the information under this item and **Exhibit 99.1** shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing. This report will not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

The Securities and Exchange Commission encourages registrants to disclose forward-looking information so that investors can better understand the future prospects of a registrant and make informed investment decisions. This Current Report on Form 8-K and exhibits may contain these types of statements, which are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, and which involve risks, uncertainties and reflect the Registrant’s judgment as of the date of this Current Report on Form 8-K. Forward-looking statements may relate to, among other things, operating results and are indicated by words or phrases such as “expects,” “should,” “will,” and similar words or phrases. These statements are subject to inherent uncertainties and risks that could cause actual results to differ materially from those anticipated at the date of this Current Report on Form 8-K. Investors are cautioned not to rely unduly on forward-looking statements when evaluating the information presented within.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	ISMRT Presentation
101	Pursuant to Rule 406 of Regulation S-T, the cover page is formatted in Inline XBRL (Inline eXtensible Business Reporting Language).
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibit 101).

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.

ALZAMEND NEURO, INC.

Dated: September 29, 2026

s/ David J. Katzoff
David J. Katzoff
Chief Financial Officer



HARVARD
Medical School



Massachusetts
General Hospital



Athinoula A.
Martinos
Center
For Biomedical Imaging

Pharmacokinetics imaging of lithium at 7T – results from a phase 1/2A clinical trial with a novel organic lithium salt

Ovidiu C. Andronesi, Katherine N. Maina, Daniel Park, May Aon, Shuqing Deng, Melanie Brown, Sara Farina, Paul Weiser, Tan-Hanh Pham, Nathaniel Mercaldo, Donald Reitberg, Eve Del Rio, Michael Henry, Kraig Roajphlastien, Stephan Jackman, Kelli S. Devitte-McKee, Alison McManus, Jessica Gerber, Steven Arnold, Hope Taft, Susie Huang, Bruce R. Rosen

ISMRM Workshop Advances in X-Nuclei MR, 29 Sept 2026



Declaration of Financial Interests or Relationships

Speaker Name: Ovidiu C. Andronesi

I have the following financial interest or relationship to disclose with regard to the subject matter of this presentation:

- Company Name: Alzamend Neuro Inc
 - Type of Relationship: Sponsored research funding
-

LITHIUM TREATMENT

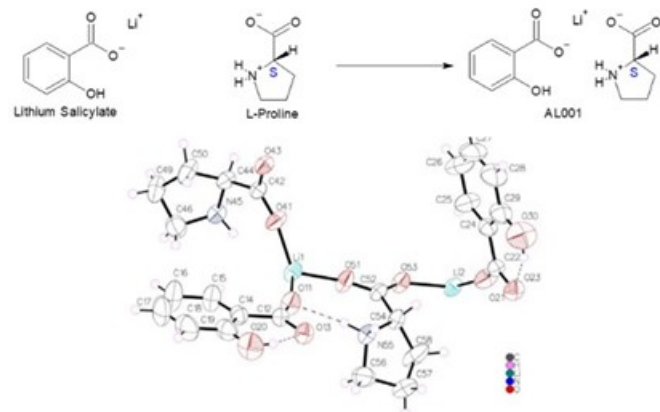


- **Lithium is the gold standard treatment for bipolar disorder**, and often used in major depressive disorder, schizophrenia or Alzheimer's disease.
 - **Clinical utility is constrained by a narrow therapeutic window for inorganic lithium salts (Li_2CO_3)** which need careful monitoring to manage renal, thyroid, and other systemic toxicity risks.
 - In this clinical trial we investigated the brain pharmacokinetics of **AL001, a novel organic co-crystal containing lithium salicylate/L-proline** designed for better brain delivery with less systemic exposure than inorganic salts.
-

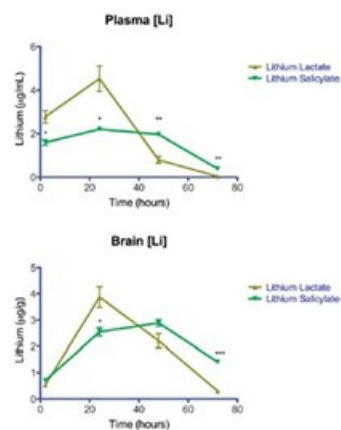
AL001



AL001 = co-crystal of Lithium salicylate + L-proline (LISPRO crystal)



Pre-clinical studies in mice indicated a better PK profile for lithium salicylate



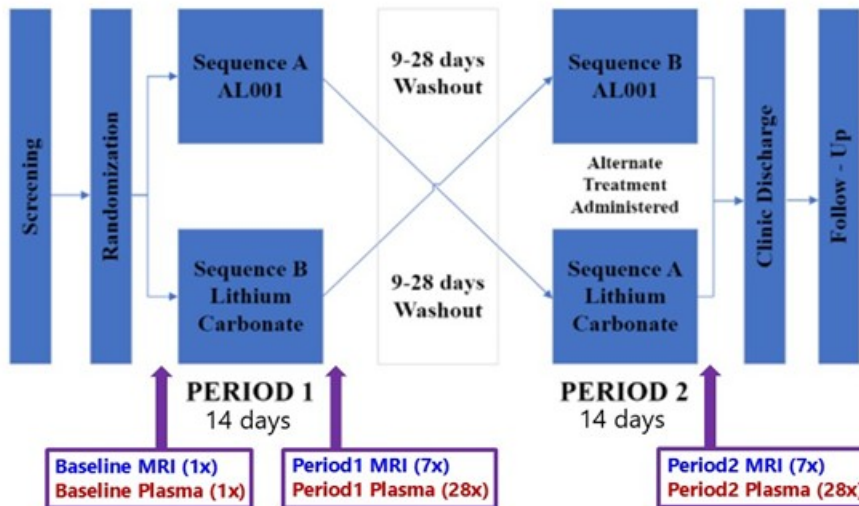
Smith A et al, RSC Adv., 2014, 4, 12362–12365

CLINICAL TRIAL DESIGN

ClinicalTrials.gov/NCT06921590



All participants receive both treatments, AL001 and Li_2CO_3



Phase 1/2a design:

- 2 treatments
- 2 periods
- randomized
- longitudinal
- cross-over

30 Participants:

- **6 Healthy**
- 6 Bipolar
- 6 Major Depression
- 6 Alzheimer
- 6 PTSD

LITHIUM IMAGING



- MR Scanner: 7T Terra.X (Siemens Healthineers)
- Dual-tuned coil: 7Li/1H 1Tx/1Tx-16Rx/16Rx (Tesla Dynamics Coil)
- Pulse sequence: 3D radial balanced SSFP (3D bSSFP)
- Image reconstruction: Regridding + density compensation (ICE on-line)
- Image processing: Super-resolution upsampling + Absolute Quantification + MNI + PK modeling

3D radial bSSFP:

- TR/TE = 10ms/5ms,
- FA = 22°,
- Voxel = 8 cm³ (20 mm iso)
- Spokes = 400,
- NA = 375,
- TA = 25:02 min:s

Image processing:

- Freesurfer + FSL + MINC + Python
 - Pipeline compliant with CFR 2.11 regulations for FDA submission
-

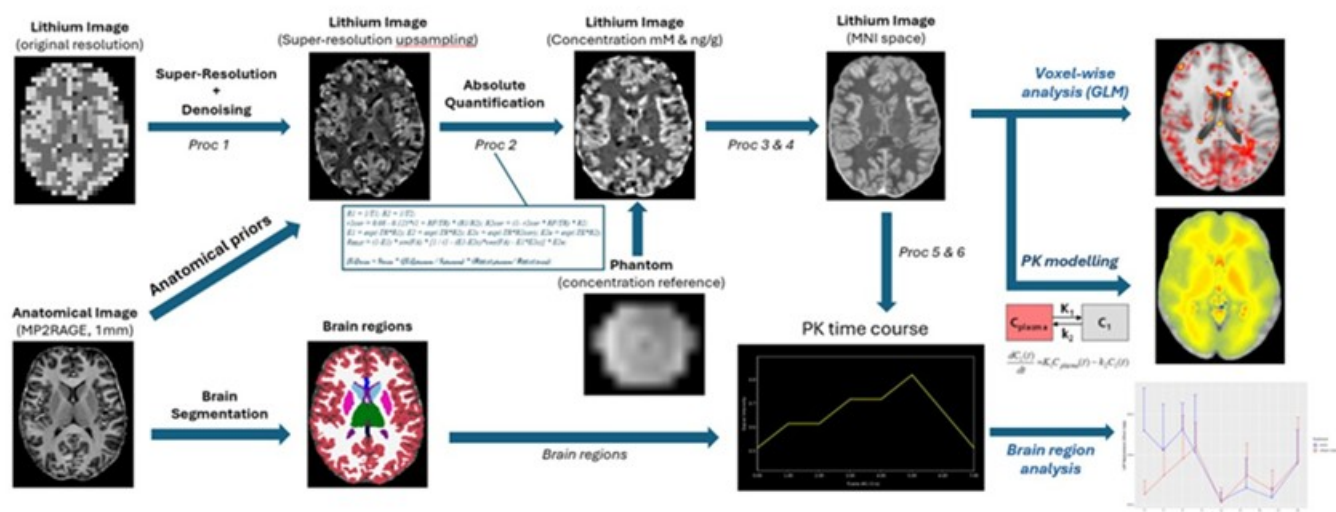


IMAGE PROCESSING PIPELINE



Super-resolution:

regularized patch based feature nonlocal means

Low-res MRSI



Super-res MRSI



Non-convex optimization

$$\hat{x} = \arg \min_x \{ \|y - H(x)\|^2 + \lambda R(x) \}$$



High-res MRI

$$R(x) = \sum_v \left| x(v) - \sum_{u \in \Omega(v)} w(v, u) x(u) \right|^2$$

Xianqi Li et al, Radiology 2020, 294, 589-597

Absolute Quantification:

bSSFP relaxation correction with finite RF pulse duration

- $R1 = 1/T1$
- $R2 = 1/T2$
- $r2_{cor} = 0.68 - 0.125 \times (1 + T_p/TR) \times (R1/R2)$
- $R2_{cor} = (1 - r2_{cor} \times T_p/TR) \times R2$
- $E1 = \exp(-TR \times R1)$
- $E2 = \exp(-TR \times R2)$
- $E2c = \exp(-TR \times R2_{cor})$
- $E2e = \exp(-TE \times R2)$
- $R_{bSSFP} = (1 - E1) \times \sin(FA) \times [1 / (1 - (E1 - E2c) \times \cos(FA) - E1 \times E2c)] \times E2e$
- $[Li]_{brain} = [Li]_{phantom} \times (S_{brain} / S_{phantom}) \times (R_{bSSFP-phantom} / R_{bSSFP-brain})$

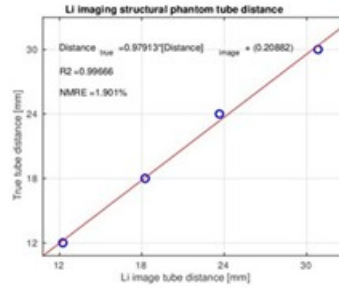
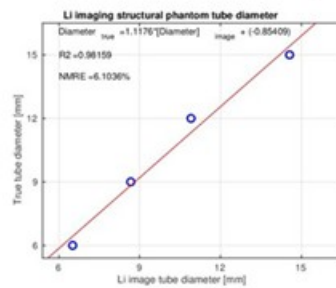
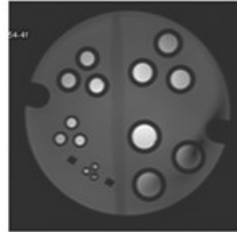
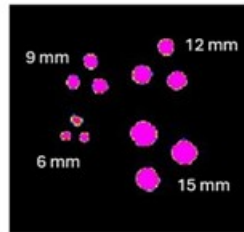
Bieri et al, MRM, 2009, 62:1232

Bernstein et al, Handbook of MRI Pulse Sequences

PHANTOM VALIDATION



Lithium image spatial resolution of 3D radial bSSFP

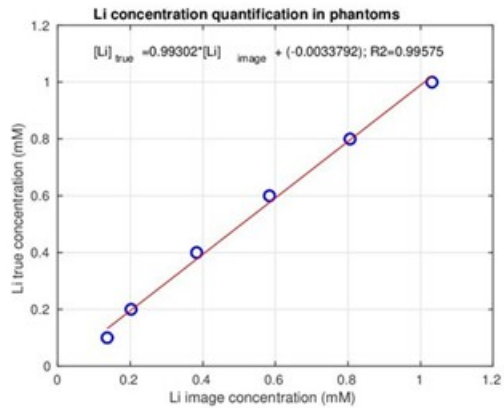


PHANTOM VALIDATION

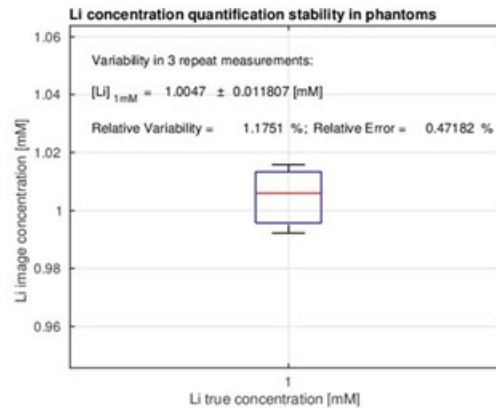


Absolute Quantification of Li concentration from bSSFP images

Linearity and lower limit of quantitation

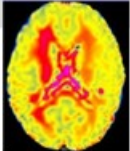
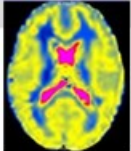
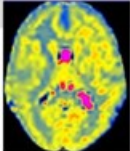
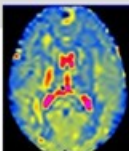
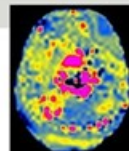


Variability: test-retest triplicates



Rating of Li Image Quality by Radiologists



Li image	Excellent (5)	Good (4)	Adequate (3)	Poor (2)	Very Poor (1)
# 1-96					

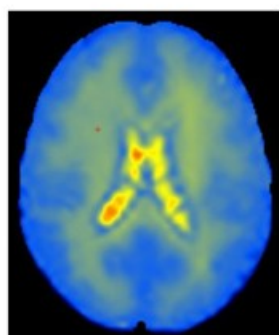
92% of images scored
Excellent-Adequate

Agreement Analysis	Gwet's Agreement Coefficient	
	Estimate (95%CI)	Landis-Koch Benchmark Label
Primary Analysis - assuming complete independence	0.73 (0.66, 0.80)	Substantial
Sensitivity Analysis - not assuming complete independence	0.61 (0.28, 0.83)	Moderate-Fair

Lithium Brain Concentration

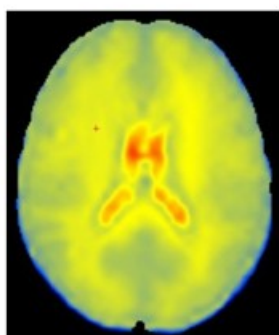


Baseline



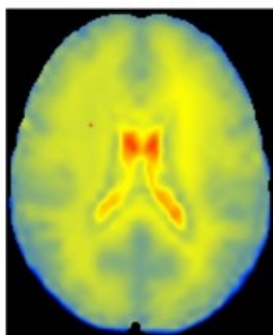
0 1
mM

AL001



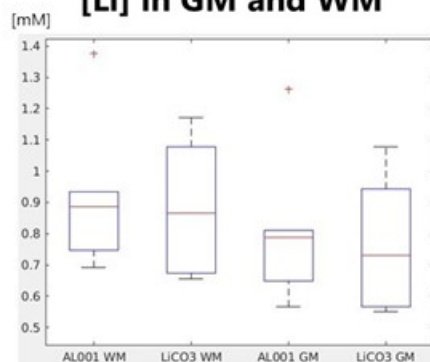
0 1
mM

Li_2CO_3



0 1
mM

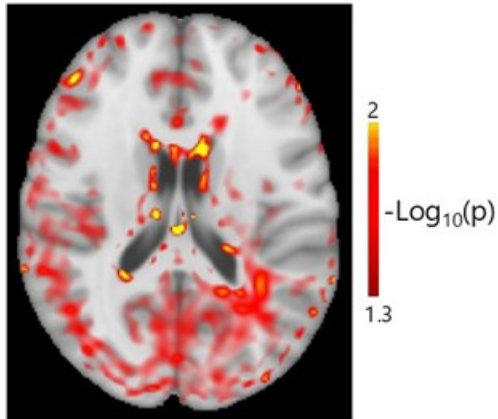
[Li] in GM and WM



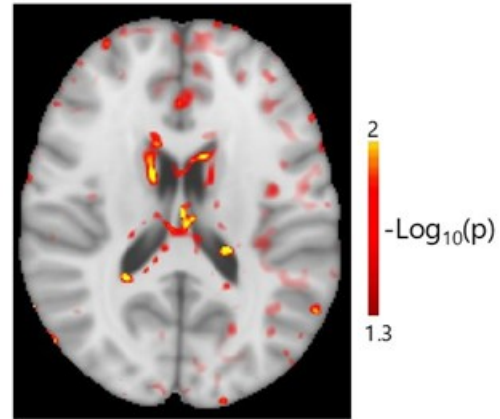
Voxel-wise General Linear Model [Li] Treatment-Baseline



AL001-Baseline



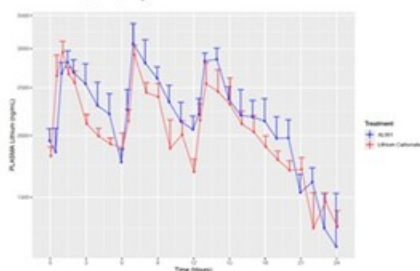
Li_2CO_3 -Baseline



PK analysis – non-compartmental model

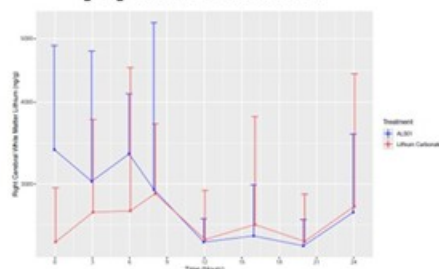


[Li] plasma



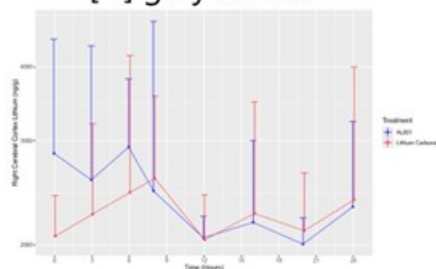
$AUC_{AL001} = 53873$ (hr*ng/mL)
 $AUC_{Li_2CO_3} = 51427$ (hr*ng/mL)

[Li] white matter



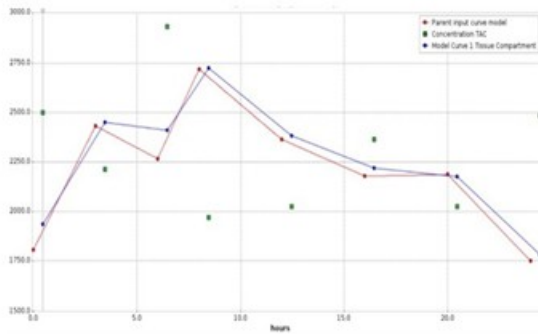
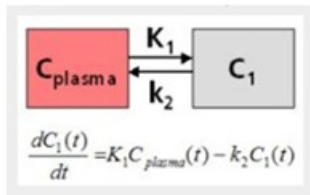
$AUC_{AL001} = 37347.73$ (hr*ng/mL)
 $AUC_{Li_2CO_3} = 33581.70$ (hr*ng/mL)

[Li] gray matter

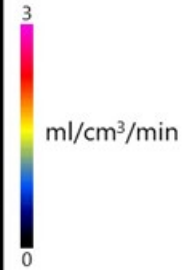
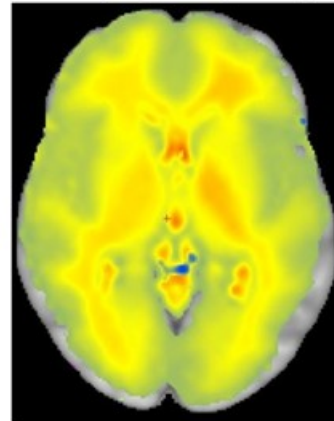


$AUC_{AL001} = 32370.77$ (hr*ng/mL)
 $AUC_{Li_2CO_3} = 29309.12$ (hr*ng/mL)

PK analysis – two-compartment model



K1 (ml/cm³/min)



Summary



- 7 Tesla provides higher SNR for lithium imaging and allows quantification of lithium concentration in the brain over the PK relevant range (0.1- 1 mM; 694-6941 ng/g) with anatomical spatial resolution.
 - Brain region analysis indicate a trend for slightly higher Li concentration after AL001 (geometric mean 4020.64 ng/g, 64% CV) compared to Li_2CO_3 (geometric mean 3476.94 ng/g, 57% CV), with slightly larger values in white matter than gray matter.
 - Voxel-wise general linear model indicate a trend for higher Li concentration in the gray matter after AL001 compared to Li_2CO_3 .
 - Non-compartment PK modelling indicate a trend for slightly higher AUC after AL001 (geometric mean 62230 h*ng/g, 26% CV) compared to Li_2CO_3 (geometric mean 59715 h*ng/g, 25% CV).
 - Two compartment PK modelling indicate higher plasma to brain transfer rate (K1) in the white matter than gray matter for AL001.
 - Differences between AL001 and Li_2CO_3 are not statistically significant, in line with the small sample size. The observed trends in the healthy cohort generate hypothesis that will be tested in subsequent patient cohorts (bipolar, major depression, Alzheimer and PTSD).
-

Acknowledgements



MGH, Department of Radiology Martinos Biomedical Imaging Center:

Katherine Maina
Paul Weiser
Tan-Hanh Pham
Nathaniel Mercaldo
May Aon
Shuqing Deng
Melanie Brown
Sarah Farina
Hope Taft
Susie Huang
Bruce Rosen

Paul Weiser



Katy Maina



Hanh Pham



Melanie Brown



Shuqing Deng



May Aon



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Eve Del Rio,
Kraig Roajphlastien,

QMENTA

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Kire Trivodaliev

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Kelli S. Devitte-McKee,
Alison McManus