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): June 22, 2026

MapLight Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-42914	83-2163243
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

800 Chesapeake Drive
Redwood City, California 94063
(Address of principal executive offices)

Registrant's telephone number, including area code: (617) 984-6300

N/A
(Former name or former address, if changed since last report.)

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
Voting Common Stock, $0.0001 par value per share	MPLT	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 June 22, 2026, MapLight Therapeutics, Inc. (the "Company") will hold a conference call to discuss the topline results from IRIS (ML-004-002), a Phase 2 study of ML-004 in autism spectrum disorder (the "IRIS Trial Results"). A copy of the presentation that will accompany the conference call is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed "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, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On June 22, 2026, the Company issued a press release announcing the IRIS Trial Results. A copy of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Company Presentation, dated June 22, 2026.
99.2	Press Release, dated June 22, 2026.
104	Cover Page Interactive Data File (formatted as inline XBRL).

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.

MapLight Therapeutics, Inc.

Dated: June 22, 2026

By: /s/ Christopher A. Kroeger
Christopher A. Kroeger, M.D.
Chief Executive Officer

Exhibit 99.1

Topline Data from Phase 2 IRIS Trial Evaluating ML-004 in Autism Spectrum Disorder

June 22, 2026

Safe Harbor and Forward-Looking Statements

This presentation and any accompanying oral commentary have been prepared by MapLight Therapeutics, Inc. ("MapLight", "we," "us," "our," the "Company", or similar terms) for informational purposes only and not for any other purpose.

This presentation contains trademarks, service marks, trade names and copyrights of MapLight and other companies which are the property of their respective owners. This presentation discusses product candidates that are under pre-clinical and clinical study, and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or efficacy of these product candidates for the uses for which they are being studied.

Statements contained in this presentation and the accompanying oral commentary, other than statements of historical facts, may be forward-looking statements, including, but not limited to statements about the clinical development and potential benefits of ML-004 and the potential patient population for ML-004. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "targets," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, timing of results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. Risks and uncertainties that may cause actual results to differ materially include risks and uncertainties that are described in the "Risk Factors" section of our Quarterly Report on Form 10-Q with the U.S. Securities and Exchange Commission ("SEC") on May 14, 2026 and other filings we make with the SEC from time to time. These documents are available under the "SEC Filings" page of the "Investors" section of our website at www.maplightrx.com.

New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially and adversely from those anticipated or implied in the forward-looking statements. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this presentation represent our views as of the date of this presentation. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. Except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements in this presentation and the accompanying oral commentary. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Agenda

Executive Summary and Key Takeaways for ML-004	Chris Kroeger, M.D.	Co-Founder and Chief Executive Officer
Phase 2 IRIS Study Results	Erin Foff, M.D., Ph.D.	Chief Medical Officer
Unmet Medical Need in ASD Irritability	Chris Kroeger, M.D.	Co-Founder and Chief Executive Officer
Closing Remarks	Chris Kroeger, M.D.	Co-Founder and Chief Executive Officer
Q&A Session	All	

Summary of IRIS Phase 2 Topline Results

Program Rationale

- **ML-004 is an IR/ER reformulation of the 5-$HT_1B/_1D$ agonist zolmitriptan**
  - Zolmitriptan demonstrates activity in both sociability and irritability/aggression animal models
    - Activation of 5-HT_1B receptors in the nucleus accumbens recapitulates the prosocial effects of MDMA
    - Aggression mechanism involves suppression of a subset of striatal D1-MSNs
- Based on preclinical findings, IRIS was designed as an exploratory study to evaluate multiple clinical endpoints in ASD

Efficacy Observations

- **IRIS (1) did not meet its primary endpoint in social communication deficits associated with ASD**
- **Clinically meaningful improvement observed in adolescents with moderate-to-severe baseline irritability (ABC-I ≥ 16) across both caregiver- and clinician-rated scales, despite small sample sizes**
  - A prespecified analysis in adolescents with baseline ABC-I ≥ 16 demonstrated meaningful improvement on the care partner-reported ABC-I vs. placebo at EOMD (ES of 1.33; nominal p=0.013)
  - Consistent with this finding, an analysis of the clinician-rated CGI-I Irritability in the same subpopulation demonstrated clinically meaningful improvement vs. placebo (ES of 1.08; nominal p=0.036)
  - Treatment effects were greater among adolescents with greater levels of baseline irritability

Safety and Tolerability

- **ML-004 was generally well-tolerated, with no severe or serious adverse events in the active treatment arm and potentially meaningful differentiation from standard of care atypical antipsychotics**
  - No extrapyramidal events were observed, and rates of sedation/somnolence were low
  - Mean weight gain was lower with ML-004 than with placebo

IR/ER = immediate release / extended release; MDMA = 3,4-methylenedioxymethamphetamine; ASD = autism spectrum disorder; ABC-I = Aberrant Behavior Checklist-Irritability; EOMD = end of maintenance dosing; ES = effect size; CGI-I = Clinical Global Impression-Improvement; 5-HT = 5-hydroxytryptamine (serotonin).
(1) Also known as ML-004-002 / NCT05081245.

Potential Future Development Considerations

Differentiation Opportunity	• Effect sizes observed in adolescents with moderate irritability are at/above those observed in clinical trials with antipsychotics currently approved for the treatment of irritability in ASD • Tolerability findings suggest potential differentiation from D_2-based atypical antipsychotics
Development Pathway	• FDA approval precedents support use of the ABC-I scale in this setting [1] • Following a full review of the data, the Company expects to engage with the FDA in an EOP2 meeting to determine the future development path
Meaningful Unmet Need	• The total addressable market for irritability in autism is large, and the unmet medical need remains high due to the limitations of existing therapies

Data support potential development of ML-004 for irritability associated with ASD, an indication with high unmet need and an established regulatory path; next steps will be guided by upcoming regulatory interactions

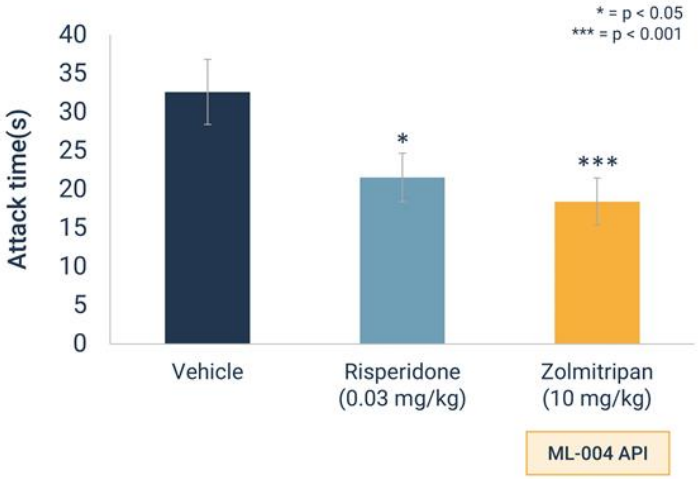
EOP2 = End-of-Phase 2; FDA = U.S. Food and Drug Administration.
(1) Approval precedents include risperidone, approved in 2006, and aripiprazole, approved in 2009, for irritability associated with ASD.

ML-004 Preclinical Findings in Aggression

Translational Rationale

- Decreased serotonin or loss of 5-HT_1B receptor function is linked to aggression in mice and humans [1][2][3][4]
- Increased serotonin or activation of 5-HT_1B receptors inhibits brain circuits associated with aggression [2]
- At clinically-relevant exposures, zolmitriptan, the API of ML-004, reduces aggression in mice to a similar degree as risperidone, an approved treatment for irritability associated with ASD
- **These findings established the rationale for evaluating irritability-related behaviors in the Phase 2 IRIS study**

Resident Intruder Aggression Assay



API = active pharmaceutical ingredient.

(1) Saudou et al, 1994
(2) Zhang et al, 2026
(3) Conner et al, 2010; Hakulinen et al, 2013
(4) da Cunha-Bang et al, 2017

MapLight

MapLight

Phase 2 Results

Erin Foff, M.D. | Chief Medical Officer

Phase 2 Study Background and Design

Background and Key Objectives

- IRIS was designed as an exploratory signal-finding study evaluating ML-004 in adolescents and adults with ASD
- Primary objective was to evaluate ML-004 vs. placebo for social communication deficits, a new indication for which there are no approved therapies
- Potential impact on irritability was a key secondary outcome measure due to strong preclinical findings
- **Study included several signal-finding considerations:**
  - Primary outcome measure without demonstrated treatment response: ABI-SC Domain Score
  - Flexible dosing allowing for exposure response analyses
  - Definition of positive efficacy signal: consistent, biologically plausible, and clinically coherent patterns across endpoints, not statistical significance alone

IRIS Study Design

- Multi-center, randomized, double-blind, placebo-controlled trial evaluating the efficacy, safety, and tolerability of ML-004
- **161 participants randomized 1:1 to ML-004 or placebo**
  - 102 adolescents ages 12-17; 59 adults ages 18-45
- **Once-daily oral bilayer IR/ER tablet formulation with flexible dosing paradigm**
  - Target maintenance dose of 48 mg or 72 mg, based on weight/contraceptive use (24 mg allowed based on tolerability)
- **Primary endpoint**: Change in ABI-SC Domain Score from baseline to end of maintenance dosing (EOMD) (1)
- **Key Secondary endpoints**:
  - CGI-I (global) and CFB to week 12 in the ABI-C
  - Change in ABC-I score from baseline to EOMD[1] for patients with ≥ moderate irritability at baseline

ABI-SC = Autism Behavioral Inventory-Social Communication; ABI-C = Autism Behavioral Inventory-Clinician Score; CFB = Change from Baseline; CGI-I = Clinician Global Impression-Improvement.
(1) Double-blind baseline to start of maintenance dosing was ~9-12 days; maintenance dose period was 12 weeks.

Efficacy Observations Across Endpoints

	Primary Endpoint	Key Secondary Endpoints			Other (1)
Scale	ABI-SC	CGI-I	ABI-C	ABC-I	CGI-I Irritability
Rater	Care-partner reported	Clinician-rated	Clinician-rated	Care-partner reported	Clinician-rated
Domain Assessed	Social Communication	Global Autism	Global Autism	Irritability (with baseline ABC-I≥16)	Irritability (with baseline ABC-I≥16)
Result	No statistical separation	No statistical separation	No statistical separation	Overall: Large ES of 0.64, not nominally statistically significant Adolescents (Prespecified): Clinically meaningful improvement vs. PBO → ES of 1.33, nominal p=0.013	Overall: Large ES of 0.61, not nominally statistically significant Adolescents: Clinically meaningful improvement vs. PBO → ES of 1.09, nominal p=0.036

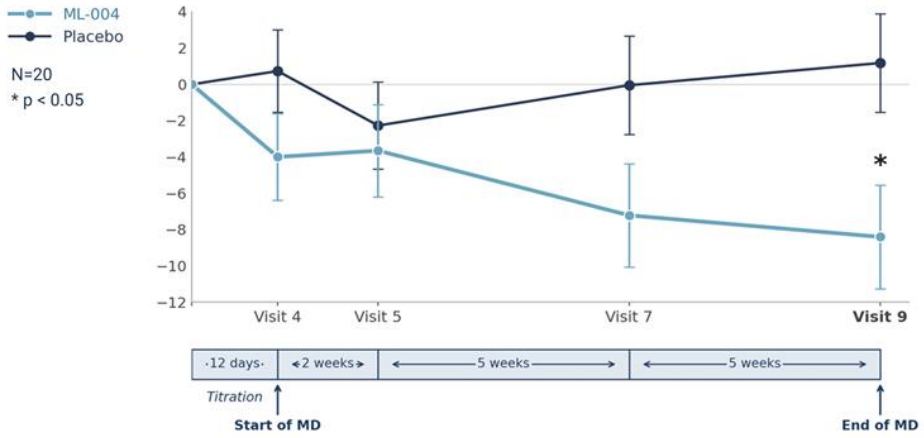
Greater treatment effect in adolescent participants with higher baseline severity

PBO = placebo.
(1) There were numerous protocol-defined secondary and exploratory endpoints.

ABC-I: Prespecified Adolescent Subgroup

Includes Subjects with ABC-I ≥16 at Baseline

Change From Baseline in ABC-I (LS Mean Difference)



	Visit 7	Visit 9
LS Mean Difference vs. PBO	-7.2	-9.6
P-value	0.052	0.013 *
Effect Size	1.00	1.33

- Numerical separation from PBO emerged early and increased through the end of maintenance dosing
- Large treatment effect at EOMD with a 9.6-point PBO-adjusted improvement

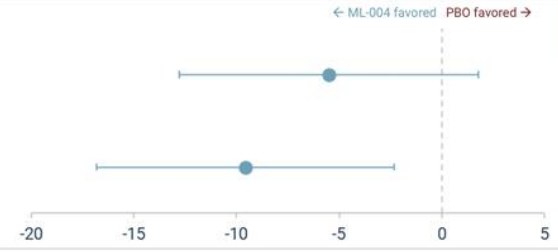
LS = least squares.
Note: Negative treatment deltas favor active treatment; effect size presented as an absolute value. Full Analysis set (FAS): The FAS includes all randomized subjects who received at least 1 dose of study drug after randomization and have DB Baseline and at least 1 post-DB Baseline assessment.

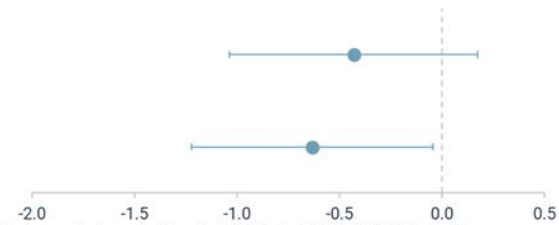
Irritability Outcomes

Includes Subjects with ABC-I ≥16 at Baseline

Two measures of irritability assessed by different raters

LS Mean Difference vs. Placebo (95% CI), by Scale and Age Group





		LS Mean Diff. [95% CI]	Effect Size	P-value (* $p < 0.05$)
ABC-I Subscale (1) *Care partner-reported*	Total N = 26	-5.5 [-12.8, 1.8]	0.64	0.131
	Adolescent N = 20	-9.6 [-16.8, -2.3]	1.33	**0.013** *
CGI-I Irritability Domain (2) *Clinician-reported*	Total N = 26	-0.4 [-1.0, 0.2]	0.61	0.153
	Adolescent N = 20	-0.6 [-1.2, -0.0]	1.08	**0.036** *

Note: Negative treatment deltas favor active treatment; effect size presented as an absolute value. Full Analysis set (FAS): The FAS includes all randomized subjects who received at least 1 dose of study drug after randomization and have DB Baseline and at least 1 post-DB Baseline assessment.

(1) ABC-I in the whole population was a key secondary endpoint evaluated in IRIS study; evaluation of change in the adolescent population was a prespecified endpoint

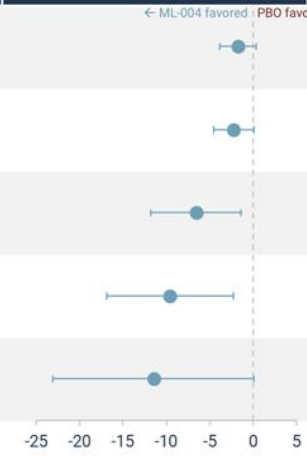
(2) CGI-I Global is included in labels for approved therapies.

Change From Baseline to End of Maintenance Dose

Adolescent Subgroup Analysis by Irritability Score at Baseline

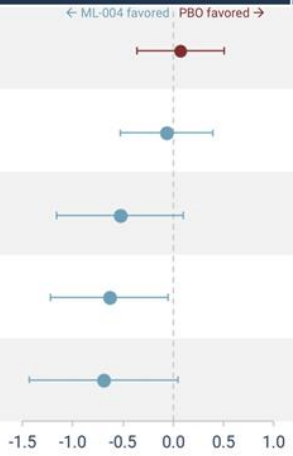
ABC-I Subscale

Subgroup N=active/PBO	LS Mean Diff [95% CI]	Effect Size	P-value (* p < 0.05)
All adolescents N = 49/51		0.34	0.107
ABC-I > 0 N = 43/48		0.43	0.054
ABC-I ≥ 13 N = 17/15		0.97	0.015 *
ABC-I ≥ 16 N = 11/9		1.33	0.013 *
ABC-I ≥ 18 N = 9/6		1.33	0.052



CGI-I Irritability Domain

Subgroup N=active/PBO	LS Mean Diff [95% CI]	Effect Size	P-value (* p < 0.05)
All adolescents N = 50/51		0.07	0.731
ABC-I > 0 N = 43/48		0.07	0.768
ABC-I ≥ 13 N = 17/15		0.64	0.097
ABC-I ≥ 16 N = 11/9		1.08	0.036 *
ABC-I ≥ 18 N = 9/6		1.16	0.065



Note: Negative treatment deltas favor active treatment; effect size presented as an absolute value. Full Analysis set (FAS): The FAS includes all randomized subjects who received at least 1 dose of study drug after randomization and have DB Baseline and at least 1 post-DB Baseline assessment.

ML-004 Was Generally Well Tolerated Across All Doses and Age Groups

Overview of Safety Observations

- Majority of TEAEs were mild, transient, and resolved without the need for dose reduction
- No severe or serious TEAEs occurred with ML-004 (all in PBO arm)
- No deaths or life-threatening events occurred
- Most frequent TEAEs (≥5% and >PBO) with ML-004 were headache, nausea, somnolence, vomiting, fatigue, and dizziness
- Adolescents experienced fewer TEAEs than adults, both overall and across common events
  - Adolescents: 62.7% for ML-004 vs. 41.2% for PBO
  - Adults: 86.7% for ML-004 vs. 72.4% for PBO
- Two adolescents discontinued (3.9%) due to a TEAE vs. 0% PBO
- Events commonly associated with commercial zolmitriptan [1] (e.g., jaw or chest pressure/tightening and paresthesia), were rare (N=1 each)

TEAE = treatment-emergent adverse event in double-blind period.
(1) ZOMIG (zolmitriptan) U.S. Prescribing Information (2018).
(2) Based on adolescent weight changes observed between the double-blind baseline and Week 12

ML-004 Safety Profile

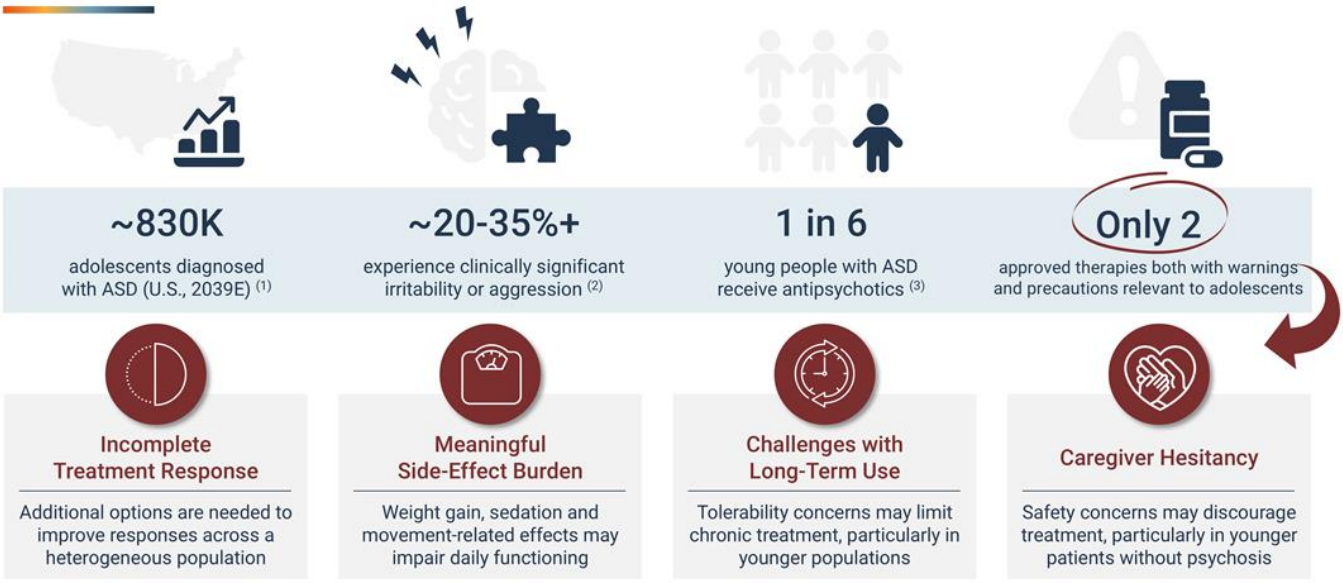
*Placebo-adjusted	Adolescents Treated with ML-004 (N=51)
Weight Gain	Mean ML-004 weight change less than PBO *+1.1kg vs. +1.9kg* [2]
Fatigue	1.9%*
Somnolence	11.8%*
Headache	9.8%*
EPS / Akathisia	Not Observed
Hyperprolactinemia / Endocrine	Not Expected
GI Effects	Nausea 9.8%*; Vomiting 5.9%*

MapLight

Unmet Medical Need

Chris Kroeger, M.D. | Co-Founder and Chief Executive Officer

Unmet Need in ASD Irritability Remains High



(1) *2039 projection of U.S. adolescents; 2022 NSCH and Grosvenor et al., 2023 claims data.*
(2) *Alatrash et al., 2024; Manter et al., BMC Medicine 2025.*
(3) *Park et al., JAACAP 2016 meta-analysis.*

Current Standard of Care in ASD Irritability

	Risperidone	Aripiprazole
Effect Size (ABC-I)	0.92 - 1.2	0.43 - 0.87
Weight Gain	**Adverse events** • Weight increased 6% (1) • Increased appetite 29% (1) **Weight change** • 1.4 kg more weight gain (2) • 26% more subjects gained ≥7% weight (2)	**Adverse events** • Decreased appetite 5% (1) **Weight change** • 1.2 kg greater weight gain (3) • 19% more subjects gained ≥ 7% weight (3)
Fatigue/Somnolence	• Fatigue 22% (1) • Sedation 48% (1)	• Fatigue 15% (1) • Lethargy 5% (1) • Somnolence 6% (1) • Sedation 17% (1)
EPS / Akathisia / Tardive Dyskinesia	• Parkinsonism 7% (1) • Tremor 7% (1)	• EPD 6% (1) • Tremor 10% (1)
Hyperprolactinemia / Endocrine	• Elevated Prolactin 47% (4) • Gynecomastia 2.3% (4)	• No adverse events reported in autism
Cardiovascular	• Warning for Orthostatic Hypotension • HR increased 1.9 bpm(3)	• Warning for Orthostatic Hypotension
GI Effects	• Constipation 11% (1) • Nausea 3% (1) • Vomiting 3% (1) • Drooling 8% (1)	• Vomiting 7% (1) • Drooling 9% (1)

Meaningful side-effect burden offers a compelling opportunity for better-tolerated treatment options

Sources: RISPERDAL® prescribing information, revised 2025; ABILIFY® prescribing information, revised 2025.
(1) PBO-adjusted double-blind short-term trials in autism, TEAE > 5% table.
(2) PBO-adjusted, pediatric patients (5 to 17 years) with schizophrenia, bipolar disorder, autistic disorder, or other psychiatric disorders. In short-term trials (3 to 8 weeks).
(3) PBO-adjusted, trials in autism (8-week duration).
(4) PBO-adjusted, 8-week trial in children and adolescents (5 to 17 years) with autistic disorder or psychiatric disorders.

ML-004 Has the Potential to Address Unmet Needs Through Established Development Path

Potential Differentiation with ML-004

Initial efficacy signal from IRIS appears in line with approved therapies [1]

- ✓ Clinically meaningful improvement observed across ABC-I and CGI-I in adolescents with elevated irritability
- ✓ Magnitude of effect appears comparable to approved therapies, based on cross-trial comparisons

Potential for differentiated tolerability profile

- ✓ No signal for weight gain or EPS; low rates of somnolence, particularly among adolescents
- ✓ Most AEs were mild and transient, with no severe or serious AEs with ML-004

5-$HT_1B/_1D$ agonism may offer patients and caregivers an alternative approach to current D_2-based therapies

Historical Development Precedents [2]

- **Efficient trial designs supported prior approvals**
  - Pivotal studies were 8 weeks and generally enrolled approximately 100 patients
- **Focused clinical programs**
  - Studies generally conducted in the U.S. across a limited number of sites [3]
- **Established regulatory endpoint**
  - ABC-I served as the primary efficacy endpoint supporting prior approvals

(1) Cross-trial comparisons are inherently limited due to differences in study design, patient populations and analytical methods.
(2) RISPERDAL® prescribing information, revised 2025; ABILIFY® prescribing information, revised 2025.
(3) Based on publicly disclosed study designs of RISPERDAL® and ABILIFY® for irritability associated with ASD.

MapLight

Closing Remarks

Chris Kroeger, M.D. | Co-Founder and Chief Executive Officer

Closing Remarks

01 ML-004 demonstrated clinically meaningful improvements in irritability in adolescents with moderate or greater baseline irritability across both caregiver- and clinician-rated scales

- ABC-I (effect size of 1.33, nominal p-value of 0.013)
- CGI-I irritability (effect size of 1.08, nominal p-value of 0.036)

02 ML-004 was generally well tolerated across all doses and age groups

- No drug-related severe or serious AEs
- Meaningful differentiation from standard of care atypical antipsychotics
  - No weight gain relative to placebo
  - No evidence of extrapyramidal symptoms
  - Low rates of fatigue / somnolence

Data support potential development of ML-004 for irritability associated with ASD, an indication with high unmet need and an established regulatory path; next steps will be guided by upcoming regulatory interactions

Advancing a Broad and Diversified Pipeline

Program	Circuit	Indications	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
ML-007C-MA M_1/M_4 agonist co-formulated with PAC	Direct and Indirect Pathways	Schizophrenia			ZEPHYR		**Topline results by mid-August 2026**
		Alzheimer's Disease Psychosis		Fast Track	VISTA		Topline results in 2H 2027
ML-004 5-$HT_{1B/1D}$ agonist	Dorsal Raphe to Nucleus Accumbens	Autism Spectrum Disorder Sociability/Irritability			IRIS		**Engage with FDA at EOP2 meeting**
ML-009 GPR52 PAM	Indirect Pathway	Hyperactivity/Impulsivity					Complete IND-enabling studies in 2027
ML-055 Next-Gen M_1/M_4 agonist	Direct and Indirect Pathways	Neuropsychiatric Disorders					Nominate preclinical candidate in 2026
ML-021 M_4 antagonist	Direct Pathway	Parkinson's Disease					Finalize preclinical candidate in 2027

Potential in other indications being explored

Leveraging our versatile circuit-based discovery platform for ongoing pipeline expansion

GPR = G-protein-coupled receptor. PAC = peripherally acting anti-cholinergic. PAM = positive allosteric modulator.

MapLight

MapLight

Q&A

MapLight Announces Topline Results from Phase 2 IRIS Study for ML-004 in Autism Spectrum Disorder

- *The IRIS Phase 2 trial did not meet its primary endpoint in social communication deficits associated with ASD*
- *A prespecified analysis in adolescents with moderate to severe baseline irritability (ABC-I ≥ 16) demonstrated meaningful improvement on the care partner-reported ABC-I over placebo (effect size 1.33, nominal p=0.013). Consistent with this, analysis of the clinician-rated CGI-I in the irritability domain for the same subpopulation demonstrated clinically meaningful improvement over placebo (effect size 1.08, nominal p=0.036). Treatment effects were greater among adolescents with greater levels of baseline irritability*
- *ML-004 was generally well-tolerated, with no severe or serious adverse events in the active treatment arm. No extrapyramidal events were observed, and mean weight gain was lower with ML-004 than with placebo*
- *Following a full review of the data, the Company expects to engage with the U.S. Food and Drug Administration (FDA) in an End-of-Phase 2 meeting to determine the clinical development path forward*
- *The Company remains well capitalized ahead of the topline results from its Phase 2 ZEPHYR trial evaluating ML-007C-MA in schizophrenia, expected by mid-August 2026*
- *Company to host live webcast today at 8:00 AM ET*

SAN FRANCISCO and BOSTON, June 22, 2026 (GLOBE NEWSWIRE) — MapLight Therapeutics, Inc. (Nasdaq: MPLT), a clinical-stage biopharmaceutical company focused on improving the lives of patients suffering from debilitating central nervous system disorders, today announced topline results from IRIS (ML-004-002), a Phase 2 study of ML-004 in autism spectrum disorder (ASD). The study randomized 161 participants (102 adolescents, 59 adults), with prespecified analyses planned by age group and baseline irritability severity.

As an exploratory signal-finding Phase 2 study, IRIS was explicitly designed to test multiple clinical endpoints based on preclinical findings, including social communication and irritability, and to identify the most appropriate development path forward. The study did not meet its primary endpoint of change from baseline to Week 12 in the caregiver-reported Autism Behavioral Inventory (ABI)–Social Communication Domain score. Social communication is a domain for which no approved pharmacologic therapies exist, and for which validated, treatment-sensitive outcome measures remain an area of active scientific investigation.

However, in a prespecified analysis of adolescents (age 12–17) with moderate or greater baseline irritability (double-blind baseline ABC-I score ≥16, N=20), ML-004 demonstrated a clinically meaningful improvement in irritability over placebo as measured by change from baseline in the care-partner reported ABC-I subscale (LS mean difference vs. Placebo -9.58, ES=1.33, nominal p value=0.013). Consistent with this finding, clinically meaningful improvement over placebo was observed on the Clinician Global Impression-Improvement (CGI-I)-Irritability domain in the adolescent population randomized with moderate or greater baseline irritability (LS mean difference -0.63; ES=1.08, nominal p value=0.036). The treatment effects on the ABC-I and CGI-I irritability domain were more pronounced among adolescents with greater baseline irritability. In the total population of participants (age 12-45) with baseline ABC-I score ≥16 (N=26), ML-004 demonstrated an effect size of 0.64 (nominal p-value =0.13) on the key secondary endpoint of change from baseline in the ABC-I score at week 12.

“We are very encouraged by the robust improvements observed in adolescents with clinically significant irritability,” said Erin Pennock Foff, Chief Medical Officer. “These results are consistent with our compelling pre-clinical evidence for reduction in aggression/irritability in animal models. Given that there is an established regulatory path in this indication using the ABC-I, and given the magnitude of the effect on this measure observed in this study, we look forward to engaging with the FDA to discuss a possible path forward. We are grateful to the participants, families, and investigators whose commitment made this trial possible.”

“Irritability is a pressing clinical problem in adolescents with autism, and the only approved pharmacologic options are antipsychotics, which carry substantial metabolic and neurological burdens,” said Matthew State, M.D. Ph.D (Chair of Psychiatry and Behavioral Sciences at the University of California, San Francisco (UCSF) and member of MapLight’s Scientific Advisory Board). “An effect size of this magnitude, particularly in those most severely affected, points to a clinically meaningful improvement and warrants further investigation of ML-004 in this population.”

Safety and Tolerability

ML-004 was generally well-tolerated, with treatment-emergent adverse events (TEAEs) that were all mild to moderate in severity. Adolescents experienced fewer TEAEs than adults (Adolescent TEAEs: 62.7% for ML-004 versus 41.2% for placebo; Adult TEAEs: 86.7% for ML-004 versus 72.4% for placebo).

- There were no SAEs or severe AEs reported in the ML-004 treated participants; among placebo-treated participants, two experienced a severe TEAE and one experienced a serious adverse event
- In the randomized population, the most common TEAEs (≥5% in ML-004 arm and >placebo) were headache, nausea, somnolence, vomiting, fatigue, and dizziness
- No events of extrapyramidal TEAEs were observed with active treatment. The mean weight gain over the course of the study was lower for ML-004 than placebo

- In adolescents, the most common adverse events (occurring in ≥5% of ML-004–treated adolescents and at least twice the rate of placebo) were headache (13.7% vs. 3.9%), somnolence (11.8% vs. 0%), nausea (9.8% vs. 0%), and vomiting (5.9% vs. 0%)
- Two (3.9%) adolescents in the active arm discontinued the study due to an adverse event (0% for placebo)

Live Webcast

The Company will host a live webcast to discuss the IRIS results in greater detail at 8:00 a.m. ET today, Monday, June 22, 2026. To access the live webcast, please visit the "Events and Presentations" page within the Investors section of the Maplight website https://ir.maplightrx.com/news-events/events-presentations. An archived replay will also be available on the website for at least 90 days following the event.

About ML-004 and IRIS

ML-004 is an immediate-release, or IR, and extended-release, or ER, formulation of zolmitriptan, a 5-HT1B/1D agonist currently approved for the acute treatment of migraine. The Phase 2 IRIS trial (NCT05081245) is a randomized, double-blind, placebo-controlled trial evaluating the efficacy, safety, and tolerability of ML-004 in adults (age 18-45) and adolescents (age 12-17) with autism spectrum disorder. A total of 161 participants were randomized, inclusive of 102 adolescents.

About MapLight Therapeutics

MapLight Therapeutics is a clinical-stage biopharmaceutical company focused on improving the lives of patients suffering from debilitating central nervous system disorders. The Company was founded by globally recognized leaders in psychiatry and neuroscience research to address the lack of circuit-specific pharmacotherapies available to patients. The Company's discovery platform holds the potential to fill this void by identifying neural circuits causally linked to disease and targeting those circuits for therapeutic modulation.

For more information, please visit www.maplightrx.com.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, the clinical development and potential benefits of ML-004. Words such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "develop," "plan" or the negative of these terms, and similar expressions, are intended to identify forward-looking statements. While the Company believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to the Company on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in the

Company's filings with the U.S. Securities and Exchange Commission (SEC)), many of which are beyond the Company's control and subject to change. Actual results could be materially different. Risks and uncertainties include: the unpredictable relationship between preclinical study results and clinical study results; the risk that results obtained in any clinical trials to date may not be indicative of results obtained in ongoing or future trials; the timing or likelihood of regulatory filings and approvals; expectations regarding the Company's ability to fund its current operations; and other risks and uncertainties identified in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, and subsequent disclosure documents the Company may file with the SEC. The Company claims the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. The Company expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

For investor inquiries: investors@maplightrx.com

For media inquiries: media@maplightrx.com