

2023 Medicines in Development – Mental Illness

Anxiety Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ALTO-100 (brain-derived neurotrophic factor)	Alto Neuroscience Los Altos, CA	post-traumatic stress disorder (PTSD)	Phase II www.altoneuroscience.com
ALTO-202 (NMDA NR2B)	Alto Neuroscience Los Altos, CA	PTSD	Phase II www.altoneuroscience.com
AVP-786 (deudextromethorphan analogue/ quinidine)	Avanir Pharmaceuticals Aliso Viejo, CA	agitation in Alzheimer's disease (Fast Track)	Phase III www.avanir.com
Auvelity™ dextromethorphan and bupropion	Axsome Therapeutics New York, NY	agitation in Alzheimer's disease (Fast Track) (Breakthrough Therapy)	Phase III www.axsome.com
BI 1358894 (TRPC 4/5 channel inhibitor)	Boehringer Ingelheim Ridgefield, CT	PTSD	Phase II www.boehringer-ingelheim.com
BNC210 (alpha 7 nicotinic acetylcholine receptor)	Bionomics Adelaide, Australia,	PTSD (Fast Track), social anxiety disorder (Fast Track)	Phase II www.bionomics.com.au
cannabidiol	Anada Scientific Greenwood Village, CO	PTSD, social anxiety disorder	Phase II www.anadascientific.com

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<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
cannabidiol (synthetic)	EmpowerPharm Burlington, Ontario	social anxiety disorder	Phase II www.empowerpharm.ca
COMP360 (psilocybin) (serotonin 2 receptor agonist)	COMPASS Pathways London, United Kingdom	PTSD	Phase II www.compasspathways.com
CVL-865 (darigabat) (GABA-A PAM)	Cerevel Therapeutics Cambridge, MA	panic disorder	Phase I www.cerevel.com
EMP-01 (MDMA derivative)	EmpathBio New York, NY	PTSD	Phase I www.empath.bio
ENX-102 (GABA-A modulator)	Engrail Therapeutics San Diego, CA	generalized anxiety disorder	Phase I www.engrail.com
GRX-917 (deuterated etifoxine)	GABA Therapeutics Newport Beach, CA	generalized anxiety disorder	Phase I www.gabarx.com
HB-01	Honeybrains Biotech New York, NY	panic disorder	Phase II
Igalmi [®] dexmedetomidine	BioXcel New Haven, CT	agitation in Alzheimer's disease (Breakthrough Therapy), agitation in schizophrenia, agitation in bipolar I or II disorder	Phase III www.bioxcel.com

Anxiety Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
INP105 (olanzapine) (drug-device combination)	Impel Pharmaceuticals Seattle, WA	acute agitation and aggression associated with autism spectrum disorder	Phase I www.impelpharma.com
ITI-1284 ODT-SL (lumateperone deuterated)	Intra-Cellular Therapies New York, NY	agitation in probable Alzheimer's disease	Phase I www.intracellulartherapies.com
JZP150 (fatty acid amide hydrolase inhibitor)	Jazz Pharmaceuticals Dublin, Ireland	PTSD (Fast Track)	Phase II www.jazzpharma.com
Lu AG06466 (MAGL inhibitor)	Lundbeck Deerfield, IL	PTSD	Phase I www.lundbeck.com
MDMA (methylenedioxymethamphetamine)	Multidisciplinary Association for Psychedelic Studies San Jose, CA	PTSD (Breakthrough Therapy)	Phase III www.maps.org
MM-120 (LSD D-tartrate)	Mind Medicine New York, NY	generalized anxiety disorder	Phase II www.mindmed.co
NMRA-511 (V1aR antagonist)	Neumora Therapeutics Watertown, MA	anxiety disorder	Phase I www.neumoratx.com
NYX-783 (NMDA receptor modulator)	Aptinyx Evanston, IL	PTSD (Fast Track)	Phase II www.aptinyx.com

Anxiety Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
PH94B nasal spray (chemoreceptor cell modulator)	VistaGen Therapeutics South San Francisco, CA	social anxiety disorder (Fast Track)	Phase III www.vistagen.com
		adjustment disorder with anxiety	Phase II www.vistagen.com
Rexulti [®] brexpiprazole (oral)	Lundbeck Deerfield, IL Otsuka Pharmaceutical Rockville, MD	agitation in Alzheimer's disease (Fast Track), PTSD	Phase III www.lundbeck.com www.otsuka.com
RG7314 (balovaptan) (vasopressin 1 receptor antagonist)	Roche/Genentech South San Francisco, CA	PTSD	Phase II www.roche.com
RLS102 (cannabidiol SNAC oral)	Receptor Life Sciences Seattle, WA	agitation in autism spectrum disorder	Phase I www.receptorlife.com
RLS103 (cannabidiol inhaled dry powder)	Receptor Life Sciences Seattle, WA	acute anxiety in social anxiety disorder	Phase I/II www.receptorlife.com
seltorexant (orexin type-2 antagonist)	Janssen Research & Development Raritan, NJ	probable Alzheimer's disease with significant agitation/aggression	Phase II www.janssen.com
SEP-380135	Sunovion Pharmaceuticals Marlborough, MA	agitation in Alzheimer's disease	Phase I www.sunovion.com

Anxiety Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SYNP-101 (synthetic psilocybin)	Ceruvia Lifesciences Greenwich, CT	obsessive compulsive disorder	Phase I www.ceruvialifesciences.com
TNX-102 SL (cyclobenzaprine sublingual)	Tonix Pharmaceuticals New York, NY	PTSD (Breakthrough Therapy)	Phase II www.tonixpharma.com
TNX-601 ER (naloxone/tianeptine)	Tonix Pharmaceuticals New York, NY	PTSD	Phase I www.tonixpharma.com
troriluzole (BHV-4157) (glutamate modulator)	Biohaven New Haven, CT	obsessive compulsive disorder	Phase III www.biohaven.com
VQW-765 (alpha-7 nicotinic acetylcholine receptor agonist)	Vanda Pharmaceuticals Washington, DC	performance anxiety	Phase II www.vandapharma.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ABV-1505 (NET inhibitor)	ABVC BioPharma Fremont, CA	ADHD	Phase II www.abvcpharma.com
ADAIR (dextroamphetamine)	Vallon Pharma Philadelphia, PA	attention-deficit/hyperactivity disorder (ADHD)	Phase I www.vallon-pharma.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
centanafadine (EB-1020) (triple reuptake inhibitor)	Otsuka Pharmaceutical Rockville, MD	ADHD	Phase III www.otsuka.com
CTx-1301 (dexamethylphenidate (controlled release)	Cingulate Kansas City, KS	ADHD	Phase II www.cingulate.com
CX-717 (AMPA receptor modulator)	RespireRx Pharmaceuticals Glen Rock, NJ	ADHD	Phase II www.respirerx.com
MM-120 (LSD D-tartrate)	Mind Medicine New York, NY	ADHD	Phase II www.mindmed.co
SKL13865 (adrenergic and dopamine uptake inhibitor)	SK Life Science Paramus, NJ	ADHD	Phase I www.sklifescienceinc.com
solriamfetol (dopamine and norepinephrine reuptake inhibitor)	Axsome Therapeutics New York, NY	ADHD	Phase II www.axsome.com

Bipolar Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
aripiprazole two-month long-acting injectable	Lundbeck Deerfield, IL Otsuka Pharmaceutical Rockville, MD	bipolar 1 disorder	application submitted www.lundbeck.com www.otsuka.com
Caplyta [®] lumateperone	Intra-Cellular Therapies New York, NY	mixed features in bipolar depression	Phase III www.intracellulartherapies.com
Fanapt [®] iloperidone	Vanda Pharmaceuticals Washington, DC	bipolar 1 disorder	Phase III www.vandapharma.com
JNJ-8942 (purinergic P2X7 antagonist)	Janssen Research & Development Raritan, NJ	bipolar disorder	Phase II www.janssen.com
Lybalvi [®] olanzapine and samidorphan	Alkermes Waltham, MA	bipolar 1 disorder (pediatric)	Phase III www.alkermes.com
LYN-005 (risperidone extended release)	Lyndra Therapeutics Watertown, MA	bipolar 1 disorder	Phase II www.lyndra.com
NRX-100/NRX-101 (ketamine, D-cycloserine/lurasidone)	NRx Pharmaceuticals Radnor, PA	severe bipolar depression in patients with acute suicidal ideation and behavior (Fast Track) (Breakthrough Therapy)	Phase III www.nrxpharma.com

Bipolar Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NRX-101 (D-cycloserine/lurasidone)	NRx Pharmaceuticals Radnor, PA	bipolar depression in patients with sub-acute suicidal ideation and behavior	Phase II www.nrxpharma.com
Rykindo® risperidone extended-release microsphere for injection	Luye Pharma Princeton, NJ	bipolar disorder	application submitted www.luye.cn
SEP-4199 (serotonin receptor modulator)	Sunovion Pharmaceuticals Marlborough, MA	bipolar 1 depression	Phase III www.sunovion.com
SEP-378608	Sunovion Pharmaceuticals Marlborough, MA	bipolar depression	Phase I www.sunovion.com
SKL-PSY (serotonin 1A receptor agonist)	SK Life Science Paramus, NJ	bipolar disorder	Phase I www.sklifescienceinc.com
Vraylar® cariprazine	AbbVie North Chicago, IL	bipolar 1 disorder with depression (pediatric)	Phase III www.allergan.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ABV-1504 (NET inhibitor)	ABVC BioPharma Fremont, CA	major depressive disorder	Phase II www.abvcpharma.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ABV-1601 (NET inhibitor)	ABVC BioPharma Fremont, CA	major depressive disorder in cancer patients	Phase II www.abvcpharma.com
ABX-002 (thyroid receptor beta agonist)	Autobahn Therapeutics San Diego, CA	major depressive disorder	Phase I www.autobahntx.com
ALTO-100 (brain-derived neurotrophic factor)	Alto Neuroscience Los Altos, CA	major depressive disorder	Phase II www.altoneuroscience.com
ALTO-202 (NMDA NR2B)	Alto Neuroscience Los Altos, CA	major depressive disorder	Phase II www.altoneuroscience.com
ALTO-300	Alto Neuroscience Los Altos, CA	major depressive disorder	Phase I www.altoneuroscience.com
ANC-501 (vasopressin 1b antagonist)	EmbarkNeuro Oakland, CA	major depressive disorder	Phase II www.embarkneuro.com
apimostinel (GATE-202) (NMDA modulator)	Gate Neurosciences Carmel, IN	acute severe major depressive disorder	Phase II www.gateneuro.com
aticaprant (opioid kappa receptor antagonist)	Janssen Research & Development Raritan, NJ	major depressive disorder (adjunctive therapy)	Phase III www.janssen.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
BI 1358894 (TRPC 4/5 channel inhibitor)	Boehringer Ingelheim Ridgefield, CT	major depressive disorder	Phase II www.boehringer-ingelheim.com
BI 1569912 (NMDA regulator)	Boehringer Ingelheim Ridgefield, CT	major depressive disorder	Phase I www.boehringer-ingelheim.com
BR11-296 (GABA-A modulator)	Brii Biosciences Durham, NC	postpartum depression (treatment and prevention)	Phase I www.briibio.com
Caplyta® lumateperone	Intra-Cellular Therapies New York, NY	major depressive disorder (adjunctive therapy)	Phase III www.intracellulartherapies.com
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		mixed feature in major depressive disorder	Phase II www.intracellulartherapies.com
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centanafadine (EB-1020) (triple reuptake inhibitor)	Otsuka Pharmaceutical Rockville, MD	major depressive disorder	Phase II/III www.otsuka.com
CLE-100 (NMDA receptor antagonist)	Clexio Biosciences Tikvah, Israel	major depressive disorder (adjunctive therapy)	Phase II www.clexio.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
COMP360 (psilocybin) (serotonin 2 receptor agonist)	COMPASS Pathways London, United Kingdom	treatment-resistant depression (Breakthrough Therapy)	Phase III www.compasspathways.com
CT-152 (digital therapeutic)	Click Therapeutics New York, NY	major depressive disorder	Phase III www.clicktherapeutics.com
CTC-501 (dopamine D2/D3 receptor agonist)	Chase Therapeutics Washington, DC	major depressive disorder	Phase II www.chasetherapeutics.com
CVL-354 (KOR antagonist)	Cerevel Therapeutics Cambridge, MA	major depressive disorder	Phase I www.cerevel.com
CYB003 (deuterated psilocybin analog)	Cybin Toronto, Canada	major depressive disorder	Phase I www.cybin.com
DGX-001 (central nervous system stimulant)	Digestome Therapeutics San Francisco, CA	depression	Phase I www.digestometx.com
DSP-3456 (mGluR 2/3 NAM)	Sunovion Pharmaceuticals Marlborough, MA	treatment resistant depression	Phase I www.sunovion.com
ETX-155 (GABA A receptor modulator)	Eliem Therapeutics Redmond, WA	major depressive disorder	Phase I www.eliemtx.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
EVX-101 (carbidopa/oxyriptan)	Evecxia Research Triangle Park, NC	treatment resistant depression (adjunctive therapy)	Phase I www.evecxia.com
EVX-301 (serotonin receptor agonist)	Evecxia Research Triangle Park, NC	acute suicidal ideation in depression	Phase I www.evecxia.com
Igalmi® dexmedetomidine	BioXcel New Haven, CT	major depressive disorder (adjunctive therapy)	Phase I www.bioxcel.com
ITI-1284 ODT-SL (lumateperone deuterated)	Intra-Cellular Therapies New York, NY	depressive disorders in the elderly	Phase I www.intracellulartherapies.com
liafensine (DB104) (norepinephrine/dopamine/ serotonin reuptake inhibitor)	Denovo Biopharma San Diego, CA	treatment resistant depression	Phase II www.denovobiopharma.com
LPCN1154 (GABA A receptor modulator)	Lipocine Salt Lake City, UT	postpartum depression	Phase I www.lipocine.com
MIJ821 (NR2B negative allosteric modulator)	Novartis Pharmaceuticals East Hanover, NJ	major depressive disorder with acute suicidal ideation or behavior	Phase II www.novartis.com
MK-1942	Merck Kenilworth, NJ	treatment resistant depression	Phase II www.merck.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NBI-1065845 (AMPA receptor modulator)	Neurocrine Biosciences San Diego, CA	major depressive disorder (inadequate response to treatment)	Phase II www.neurocrine.com
NBI-1065846 (AMPA receptor modulator)	Neurocrine Biosciences San Diego, CA	anhedonia in major depressive disorder	Phase II www.neurocrine.com
NBI-1070770	Neurocrine Biosciences San Diego, CA	major depressive disorder	Phase I www.neurocrine.com
NMRA-140 (KOR antagonist)	Neumora Therapeutics Watertown, MA	major depressive disorder	Phase II www.neumoratx.com
NV-5138 (mTORC1 protein stimulant)	Navitor Pharmaceuticals Cambridge, MA Supernus Pharmaceuticals Rockville, MD	treatment resistant depression	Phase II www.navitorpharma.com www.supernus.com
onabotulinumtoxinA (botulinum toxin)	Healis Therapeutics Washington, DC	major depressive disorder	Phase II www.healistera.com
PCN-101 (NMDA receptor antagonist)	Perception Neuroscience New York, NY	treatment resistant depression	Phase II www.perceptionns.com
PH10 nasal spray (chemoreceptor cell stimulant)	VistaGen Therapeutics South San Francisco, CA	major depressive disorder (Fast Track)	Phase II www.vistagen.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
REL-1017 (NMDA channel blocker)	Relmada Therapeutics Coral Gables, FL	major depressive disorder (Fast Track)	Phase III www.relmada.com
Rouxinlin [®] toludesvenlafaxine extended release	Luye Pharma Princeton, NJ	major depressive disorder	application submitted www.luye.cn
seltorexant (orexin type 2 antagonist)	Janssen Research & Development Raritan, NJ	major depressive disorder with insomnia symptoms (adjunctive therapy)	Phase III www.janssen.com
SEP-363856 (ulotaront) (TAAR1 agonist)	Sunovion Pharmaceuticals Marlborough, MA	major depressive disorder (adjunctive therapy)	Phase II/III www.sunovion.com
SEP-378614	Sunovion Pharmaceuticals Marlborough, MA	treatment resistant depression	Phase I www.sunovion.com
SP-624 (sirtuin stimulant)	Arrivo Bioventures Morrisville, NC Sirtsei Pharmaceuticals Raleigh, NC	major depressive disorder	Phase II www.arrivobio.com
SPN-820 (mTORC1 activator)	Supernus Pharmaceuticals Rockville, MD	treatment resistant depression	Phase I www.supernus.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Spravato® esketamine	Janssen Research & Development Raritan, NJ	major depressive disorder with suicide ideation (pediatric)	Phase II www.janssen.com
TAK-041 (GPR139 agonist)	Takeda Deerfield, IL	anhedonia in major depressive disorder	Phase II www.takeda.com
TAK-653 (AMPA receptor modulator)	Takeda Deerfield, IL	major depressive disorder (inadequate treatment response)	Phase II www.takeda.com
TNX-601 ER (naloxone/tianeptine)	Tonix Pharmaceuticals New York, NY	depression	Phase I www.tonixpharma.com
TS-161 (mGlu 2/3 antagonist)	Taisho Pharmaceutical Tokyo, Japan	treatment resistant depression	Phase II www.taisho.co.jp
VLS-01 (N,N-dimethyltryptamine)	Viridia Life Sciences Berlin, Germany	treatment resistant depression	Phase I www.viridia.life
XEN1101 (KCNQ potassium channel agonist)	Xenon Pharmaceuticals Burnaby, Canada	major depressive disorder	Phase II www.xenon-pharma.com
zelquistinel (GATE-251) (NMDA modulator)	Gate Neurosciences Carmel, IN	major depressive disorder (Fast Track)	Phase II www.gateneuro.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
zuranolone (GABA A receptor modulator)	Biogen Cambridge, MA Sage Therapeutics Cambridge, MA	major depressive disorder (Breakthrough Therapy) (Fast Track), postpartum depression (Fast Track)	application submitted www.sagerx.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
aripiprazole two-month long-acting injectable	Lundbeck Deerfield, IL Otsuka Pharmaceutical Rockville, MD	schizophrenia	application submitted www.lundbeck.com www.otsuka.com
AVP-786 (deudextromethorphan analogue/ quinidine)	Avanir Pharmaceuticals Aliso Viejo, CA	schizophrenia (negative symptoms)	Phase II www.avanir.com
BI 425809 (iclepertin) (glycine transporter 1 inhibitor)	Boehringer Ingelheim Ridgefield, CT	cognitive impairment associated with schizophrenia (CIAS) (Breakthrough Therapy)	Phase III www.boehringer-ingelheim.com
brilaroxazine (RP5063) (serotonin/dopamine modulator)	Reviva Pharmaceuticals Cupertino, CA	schizophrenia	Phase III www.revivapharma.com

Schizophrenia

Product Name

Sponsor

Indication

Development Phase

Caplyta® lumateperone	Intra-Cellular Therapies New York, NY	schizophrenia (prevention of relapse)	Phase III www.intracellulartherapies.com
		schizophrenia and schizoaffective disorder (pediatric), schizophrenia (long-acting injectable)	Phase I www.intracellulartherapies.com
CT-155 (digital therapeutic)	Boehringer Ingelheim Ridgefield, CT Click Therapeutics New York, NY	schizophrenia	Phase I www.boehringer-ingelheim.com
CVL-231 (emraclidine) (muscarinic M4 receptor modulator)	Cerevel Therapeutics Cambridge, MA	schizophrenia/psychosis	Phase II www.cerevel.com
DB103 (pomaglumetad)	Denovo Biopharma San Diego, CA	schizophrenia	Phase I www.denovobiopharma.com
DLP-114 (risperidone 6-12 month formulation)	Delpor South San Francisco, CA	schizophrenia	Phase I/II www.delpor.com
DSP-0038 (serotonin 5-HT2A/c receptors dual antagonist)	Sunovion Pharmaceuticals Marlborough, MA	psychosis in Alzheimer's disease	Phase I www.sunovion.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
evenamide (voltage-gated sodium channel blocker)	Newron Pharmaceuticals Morristown, NJ	schizophrenia	Phase II www.newron.com
Fanapt® iloperidone	Vanda Pharmaceuticals Washington, DC	psychosis in Parkinson's disease	Phase II www.vandapharma.com
		schizophrenia (long-acting injection)	Phase I www.vandapharma.com
Ingrezza® valbenazine	Neurocrine Biosciences San Diego, CA	schizophrenia (add-on treatment)	Phase III www.neurocrine.com
ITI-1284 ODT-SL (lumateperone deuterated)	Intra-Cellular Therapies New York, NY	dementia-related psychosis	Phase I www.intracellulartherapies.com
KarXT (M1/M4 muscarinic agonist)	Karuna Pharmaceuticals Boston, MA	psychosis in schizophrenia, psychosis in adults with inadequate response to therapy, psychosis in Alzheimer's disease	Phase III www.karunatx.com
		schizophrenia (negative and cognitive symptoms)	Phase I www.karunatx.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
LB-102 (dopamine receptor antagonist)	LB Pharmaceuticals New York, NY	schizophrenia	Phase I www.lbpharma.us
luvadaxistat (DAAO inhibitor)	Neurocrine Biosciences San Diego, CA	CIAS	Phase II www.neurocrine.com
LY03010 (paliperidone palmitate)	Luye Pharma Princeton, NJ	schizophrenia, schizoaffective disorder	Phase III www.luye.cn
Lybalvi [®] olanzapine and samidorphan	Alkermes Waltham, MA	schizophrenia (pediatric)	Phase III www.alkermes.com
mdc-IRM (risperidone long-acting injectable)	Teva Pharmaceuticals Parsippany, NJ	schizophrenia	application submitted www.tevapharm.com
mdc-TJK (olanzapine long-acting injectable)	Teva Pharmaceuticals Parsippany, NJ	schizophrenia	Phase III www.tevapharm.com
MK-8189	Merck Kenilworth, NJ	schizophrenia	Phase II www.merck.com
ML-007 (M1/M4 agonist)	MapLight Therapeutics Palo Alto, CA	schizophrenia	Phase I www.maplightrx.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NaBen (DAAO inhibitor)	SyneuRx New Taipei City, Taiwan	refractory schizophrenia, schizophrenia (adolescent), schizophrenia (adult)	Phase II/III www.syneurx.com
NBI-1117568 (muscarinic M4 receptor agonist)	Neurocrine Biosciences San Diego, CA	schizophrenia	Phase II www.neurocrine.com
Nuplazid® pimavanserin	ACADIA Pharmaceuticals San Diego, CA	schizophrenia (negative symptoms)	Phase III www.acadia-pharm.com
RG7906 (ralmitaront) (TAAR-1 agonist)	Roche Basel, Switzerland	negative symptoms associated with schizophrenia and schizoaffective disorder	Phase II www.roche.com
Risperidone ISM® risperidone extended release	Rovi Madrid, Spain	schizophrenia (monthly)	application submitted www.rovi.es
RL-007 (NMDA/GABA-B modulator)	Recognify Life Sciences Brisbane, CA	CIAS	Phase II www.recognify.life
roluperidone (MIN-101) (serotonin 2A receptor antagonist, sigma-2 receptor antagonist)	Minerva Neurosciences Waltham, MA	schizophrenia (negative symptoms)	application submitted www.minervaneurosciences.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Rykindo® risperidone extended-release microsphere for injection	Luye Pharma Princeton, NJ	schizophrenia	application submitted www.luye.cn
SEP-363856 (ulotaront) (TAAR1 agonist)	Sunovion Pharmaceuticals Marlborough, MA	schizophrenia (Breakthrough Therapy)	Phase III www.sunovion.com
		psychosis in Parkinson's disease	Phase II www.sunovion.com
SKL20540 (alpha7 nicotinic acetylcholine receptor agonist)	SK Life Science Paramus, NJ	schizophrenia	Phase I www.sklifescienceinc.com
SP-624 (sirtuin stimulant)	Arrivo Bioventures Morrisville, NC Sirtsei Pharmaceuticals Raleigh, NC	schizophrenia	Phase I www.arrivobio.com
TS-134	Taisho Pharmaceutical Tokyo, Japan	schizophrenia	Phase I www.taisho.co.jp
Vraylar® cariprazine	AbbVie North Chicago, IL	schizophrenia (pediatric)	Phase III www.abbvie.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AD04 (serotonin-3 antagonist)	ADial Pharmaceuticals Charlottesville, VA	alcohol use disorder	Phase III www.adialpharma.com
AEF0117 (CB1 receptor antagonist)	Aelis Farma Bordeaux, France	cannabis use disorder	Phase II www.aelisfarma.com
ALM006 (neuropsychotherapeutic)	Almatica Pharma Morristown, NJ	substance use disorder	Phase III www.almatica.com
ANEB-001 (cannabinoid receptor CB1 antagonist)	Anebulo Pharmaceuticals Austin, TX	cannabinoid intoxication	Phase II www.anebulo.com
AP003 (naloxone multidose nasal spray)	Emergent BioSolutions Gaithersburg, MD	opioid use disorder (overdose)	Phase I www.emergentbiosolutions.com
ASP8062 (GABA-B receptor modulator)	Astellas Pharma US Northbrook, IL	alcohol use disorder	Phase I www.astellas.com
Auvelity™ dextromethorphan and bupropion	Axsome Therapeutics New York, NY	tobacco use disorder	Phase II www.axsome.com
AZD4041 (orexin 1 receptor antagonist)	AstraZeneca Wilmington, DE	opioid use disorder	Phase I www.astrazeneca.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
BICX104 (naltrexone implantable pellet)	BioCorRx Anaheim, CA	opioid use disorder	Phase I www.biocorr.com
cannabidiol	Anada Scientific Greenwood Village, CO	opioid use disorder	Phase II www.anadascientific.com
CVL-354 (KOR antagonist)	Cerevel Therapeutics Cambridge, MA	substance use disorder	Phase I www.cerevel.com
cytisinicline (alpha4 beta2 nicotinic receptor agonist)	Achieve Life Sciences Seattle, WA	tobacco use disorder	Phase III www.achievelifesciences.com
		----- e-cigarette cessation	Phase II www.achievelifesciences.com
DCR-AUD (ALDH2 inhibitor)	Novo Nordisk Plainsboro, NJ	alcohol use disorder	Phase I www.novonordisk.com
DLP-160 (naltrexone implant)	Delpor Brisbane, CA	opioid use disorder (once or twice yearly treatment)	Phase I www.delpor.com
DMX-1002 (12-hydroxyibogamine)	DemeRx Miami, FL	opioid use disorder	Phase I/II www.demerx.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
EMB-001 (metyrapone/oxazepam)	Embera NeuroTherapeutics Boston, MA	cocaine use disorder, tobacco use disorder	Phase II www.emberaneuro.com
INDV-2000 (orexin-1 antagonist)	Indivior North Chesterfield, VA	opioid use disorder	Phase I www.indivior.com
ITI-333 (opioid receptor partial agonist/ 5HT2A and D1 receptor antagonist)	Intra-Cellular Therapies New York, NY	opioid use disorder	Phase I www.intracellulartherapies.com
IXT-m200 (chimeric mAb)	InterveXion Therapeutics Little Rock, AR	methamphetamine use disorder (Fast Track)	Phase II www.intervexion.com
KUR-101 (opioid receptor modulator)	Kures Therapeutics New York, NY	opioid use disorder	Phase I www.kures.life
LYN-014 (nicotinic receptor antagonist)	Lyndra Therapeutics Watertown, MA	opioid use disorder (Fast Track)	Phase I www.lyndra.com
MM-110 (zolunicant)	Mind Medicine New York, NY	opioid use disorder	Phase I www.mindmed.co
MN-166 (ibudilast)	MediciNova La Jolla, CA National Institute on Drug Abuse Rockville, MD	alcohol use disorder, methamphetamine use disorder (Fast Track), opioid use disorder	Phase II www.medicinova.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
OMS405 (PPAR gamma agonist)	Omeros Seattle, WA	opioid use disorder, tobacco use disorder	Phase II www.omeros.com
OMS527 (PDE7 inhibitor)	Omeros Seattle, WA	substance use disorder	Phase I www.omeros.com
OPNT002 (naltrexone nasal spray)	Opiant Pharmaceuticals Santa Monica, CA	alcohol use disorder	Phase I www.opiant.com
OPNT003 (nalmeferene nasal spray)	Opiant Pharmaceuticals Santa Monica, CA	opioid use disorder (Fast Track)	application submitted www.opiant.com
PP-01 (CB1 partial agonist/GABA modulator)	PleoPharma Phoenixville, PA	cannabis withdrawal, symptoms in cannabis use disorder	Phase II www.pleopharma.com
PT150 (glucocorticoid receptor antagonist)	Pop Test Cliffside Park, NJ	alcohol use disorder	Phase I www.poptestllc.vom
SBP-9330 (mGlu2 modulator)	Camino Pharma San Diego, CA	tobacco use disorder	Phase I www.caminopharma.com
TMP-301 (mGluR5 NAM)	Tempero Bio Oakland, CA	substance use disorder	Phase I www.temperbio.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
TNX-1300 (double mutant cocaine esterase)	Tonix Pharmaceuticals New York, NY	cocaine use disorder (Breakthrough Therapy)	Phase II www.tonixpharma.com
TRV734 (opioid mu receptor agonist)	Trevena Chesterbrook, PA National Institute on Drug Abuse North Bethesda, MD	opioid use disorder (withdrawal)	Phase II www.trevena.com

Other Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ACP-204	ACADIA Pharmaceuticals San Diego, CA	neuropsychiatric disorders	Phase I www.acadia-pharm.com
ALM007 (neuropsychotherapeutic)	Almatica Pharma Morristown, NJ	mental disorders	Phase II www.almatica.com
AVP-786 (deudextromethorphan analogue/ quinidine)	Avanir Pharmaceuticals Aliso Viejo, CA	neurobehavioral disinhibition syndrome in traumatic brain injury, intermittent explosive disorder	Phase II www.avanir.com
BHV-7000 (KV7 ion channel modulator)	Biohaven New Haven, CT	mood disorders	Phase I www.biohaven.com

Other Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
BI 1358894 (TRPC 4/5 inhibitor)	Boehringer Ingelheim Ridgefield, CT	borderline personality disorder	Phase II www.boehringer-ingelheim.com
centanafadine (EB-1020) (triple reuptake inhibitor)	Otsuka Pharmaceutical Rockville, MD	binge eating disorder	Phase II/III www.otsuka.com
COMP360 (psilocybin) (serotonin 2 receptor agonist)	COMPASS Pathways London, United Kingdom	anorexia nervosa	Phase II www.compasspathways.com
MGLLi (small molecule)	Janssen Research & Development Raritan, NJ	psychiatric disorders	Phase I www.janssen.com
OMS527 (PDE7 inhibitor)	Omeros Seattle, WA	impulse control disorder	Phase I www.omeros.com
PRX-P4-003 (novel prodrug stimulant)	Praxis BioResearch Sacramento, CA	apathy in Alzheimer's disease	Phase early 1 www.praxisbioresearch.com
RG6163	Roche/Genentech South San Francisco, CA	psychiatric disorders	Phase I www.roche.com
RG7637	Roche/Genentech South San Francisco, CA	psychiatric disorders	Phase I www.roche.com

Other Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SXC-2023 (SLC7A11 protein stimulant)	Promentis Pharmaceuticals Milwaukee, WI	moderate to severe trichotillomania (recurrent hair pulling) in adults (impulse control disorder)	Phase II www.promentispharma.com
TRYP-0082 (psilocybin) (serotonin 2 receptor agonist)	TRYP Therapeutics San Diego, CA	binge eating disorder	Phase II www.trypherapeutics.com

The content of this report has been obtained through public, government and industry sources, and the Springer "Adis Insight" database based on the latest information. Report current **as of January 4, 2023**. The medicines in this listing include medicines being developed by U.S.-based companies conducting trials in the United States abroad, PhRMA-member companies conducting trials in the United States and abroad, and foreign companies conducting clinical trials in the United States. Some products may not be in active clinical trials. The information may not be comprehensive. For more, specific information about a particular product, contact the individual company directly or go to www.clinicaltrials.gov. The entire series of *Medicines in Development* is available on PhRMA's website: www.phrma.org.

Definitions

Application Submitted—An application for marketing has been submitted by the company to the U.S. Food and Drug Administration (FDA).

Breakthrough Therapy—Upon request by a sponsor, the FDA can grant this designation to expedite the development and review of a drug or biologic intended, alone or in combination with one or more other drugs, to treat a serious or life threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically-significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug or biologic is designated as a Breakthrough Therapy, the FDA will expedite the development and review. With this designation, all Fast Track features convey to the medicine.

Fast Track—Upon request by a sponsor, the FDA can grant this designation to facilitate the development and expedite the review of a drug or biologic to treat a serious condition and fill an unmet medical need. When considering a biopharmaceutical company's request for Fast Track designation for an investigational drug or biologic, the FDA evaluates whether it will affect factors such as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one, and whether a condition can be adequately addressed by available therapy. With Fast Track designation, early and frequent communication between the FDA and the biopharmaceutical company is encouraged throughout the entire drug development and review process to help to quickly resolve any questions or issues that arise, potentially leading to an earlier approval and access by patients.

Definitions

Orphan Designation—Upon request by a sponsor, the FDA can grant special status (“orphan status”) to a drug or biologic to treat a rare disease or condition. In order to receive an orphan designation, a qualifying drug or biologic must be intended for the treatment, diagnosis, or prevention of a rare disease or condition that affects usually fewer than 200,000 people in the United States.

Phase I—Researchers test the investigational drug or biologic in a small group of people, usually between 20 and 100 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range, and identify potential side effects.

Phase II—The investigational drug or biologic is given to volunteer patients, usually between 100 and 500, to determine whether it is effective, identify an optimal dose, and to further evaluate its short-term safety.

Phase III—The investigational drug or biologic is given to a larger, more diverse patient population, often involving between 1,000 and 5,000 patients (but sometimes many more), to generate statistically significant evidence to confirm its safety and effectiveness. Phase III studies are the longest studies and usually take place in multiple sites around the world.