

2019 Medicines in Development for Mental Illnesses

Anxiety Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AVN 101 (serotonin 6 receptor antagonist)	Avineuro Pharmaceuticals Hallandale Beach, FL	anxiety disorders	Phase II www.avineuro.com
AVP-786 (deudextromethorphan analogue/ quinidine)	Avanir Pharmaceuticals Aliso Viejo, CA Concert Pharmaceuticals Lexington, MA	agitation in Alzheimer's disease (Fast Track)	Phase III www.avanir.com www.concertpharma.com
AXS-05 (bupropion/dextromethorphan fixed-dose combination)	Axsome Therapeutics New York, NY	agitation in Alzheimer's disease (Fast Track)	Phase II/III www.axsome.com
BI-1358894 (TRPC4 channel inhibitor)	Boehringer Ingelheim Ridgefield, CT	panic disorder	Phase I www.boehringer-ingelheim.com
BTRX-335140 (opioid kappa receptor antagonist)	BlackThorn Therapeutics San Francisco, CA	anxiety disorders	Phase I www.blackthornrx.com
eltoprazine (serotonin 1A/1B partial agonist)	Amarantus BioScience (Elto Pharma) New York, NY	aggression in Alzheimer's disease	Phase II www.amarantus.com
FKW00GA (serotonin 1A receptor agonist, serotonin 2A receptor antagonist)	Fabre-Kramer Pharmaceuticals Houston, TX	generalized anxiety disorder, social phobia	Phase II www.fabrekramer.com

Anxiety Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
JNJ-42165279 (fatty acid amide hydrolase inhibitor)	Janssen Research & Development Raritan, NJ	major depressive disorder with anxious distress, social anxiety disorder	Phase II completed www.janssen.com
JNJ-61393215 (orexin1 receptor inhibitor)	Janssen Research & Development Raritan, NJ	anxiety	Phase I completed www.janssen.com
NBTX-001 (NMDA receptor antagonist)	Nobilis Therapeutics Portland, OR	post-traumatic stress disorder (PTSD)	Phase II www.nobilistx.com
NYX-783 (NMDA receptor modulator)	Aptinyx Evanston, IL	PTSD (Fast Track)	Phase II www.aptinyx.com
PH94B (chemoreceptor cell modulator)	VistaGen Therapeutics South San Francisco, CA	social anxiety disorder	Phase III 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
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>
SRX246 (vasopressin 1a receptor antagonist)	Azevan Pharmaceuticals Bethlehem, PA	PTSD	Phase II www.azevan.com
		anxiety, fear	Phase I www.azevan.com
TNX-102 SL (cyclobenzaprine sublingual)	Tonix Pharmaceuticals New York, NY	PTSD	Phase III www.tonixpharma.com
		agitation in Alzheimer's disease (Fast Track)	Phase I www.tonixpharma.com
Travivo™ gepirone ER	Fabre-Kramer Pharmaceuticals Houston, TX	generalized anxiety disorder	Phase II www.fabrekramer.com
troriluzole (BHV-4157) (glutamate modulator)	Biohaven Pharmaceutical New Haven, CT	generalized anxiety disorder	Phase III www.biohavenpharma.com
		obsessive compulsive disorder	Phase II/III www.biohavenpharma.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ATS (adrenergic receptor agonist)	Noven Pharmaceuticals Miami, FL	attention-deficit/hyperactivity disorder (ADHD)	Phase II www.noven.com
centanafadine (norepinephrine, dopamine and serotonin reuptake inhibitor)	Otsuka Pharmaceutical Rockville, MD	ADHD	Phase III www.otsuka.com
CX-717 (AMPA receptor modulator)	RespireRx Pharmaceuticals Glen Rock, NJ	ADHD	Phase II completed www.respirerx.com
dasotraline (SEP-225289) (serotonin, norepinephrine and dopamine reuptake inhibitor)	Sunovion Pharmaceuticals Marlborough, MA	ADHD (pediatric and adult)	application submitted www.sunovion.com
Dyanavel® XR amphetamine extended-release	Tris Pharma Monmouth Junction, NJ	ADHD (adult)	Phase III www.trispharma.com
eltoprazine (serotonin 1A/1B partial agonist)	Amarantus BioScience (Elto Pharma) New York, NY	ADHD (adult)	Phase III www.amarantus.com
Evekeo® amphetamine sulfate	Arbor Pharmaceuticals Atlanta, GA	ADHD (adult)	Phase III www.arborpharma.com
HLD100 (dextroamphetamine sulfate modified release)	Ironshore Pharmaceuticals Durham, NC	ADHD (pediatric)	Phase II completed www.ironshorepharma.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
KP415 (serdexmethylphenidate)	KemPharm Celebration, FL	ADHD	Phase III www.kempharm.com
KP484 (serdexmethylphenidate)	KemPharm Celebration, FL	ADHD (adult)	Phase III www.kempharm.com
NLS-001 (mazindol controlled release)	NLS Pharmaceuticals Stans, Switzerland	ADHD (adult)	Phase II www.nlspharma.com
OPC-64005 (serotonin, norepinephrine and dopamine reuptake inhibitor)	Otsuka Pharmaceutical Rockville, MD	ADHD (adult)	Phase II www.otsuka.com
SKL13865 (adrenergic and dopamine uptake inhibitor)	SK Life Science Paramus, NJ	ADHD	Phase I www.sklifescienceinc.com
SPN-810 (dopamine D2 receptor antagonist)	Supernus Pharmaceuticals Rockville, MD	impulsive aggression in ADHD (pediatric) (Fast Track)	Phase III www.supernus.com
SPN-812 (adrenergic reuptake inhibitor)	Supernus Pharmaceuticals Rockville, MD	ADHD	Phase III www.supernus.com
TRN-110	Tris Pharma Monmouth Junction, NJ	ADHD (adult and pediatric)	in clinical trials www.trispharma.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Vyvanse® lisdexamfetamine	Takeda Deerfield, IL	ADHD (4-5 years)	Phase II completed www.takeda.com

Bipolar Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ALKS 3831 (olanzapine/samidorphan)	Alkermes Waltham, MA	bipolar 1 disorder	Phase III www.alkermes.com
DLP-114 (risperidone 6-12 month formulation)	Delpor South San Francisco, CA	bipolar 1 disorder	Phase I www.delpor.com
Geodon® ziprasidone	Pfizer New York, NY	bipolar 1 disorder (pediatric)	Phase III www.pfizer.com
lumateperone (ITI-007) (serotonin receptor antagonist, serotonin reuptake inhibitor, DPP modulator, glutamate receptor modulator)	Intra-Cellular Therapies New York, NY	bipolar depression	Phase III www.intracellulartherapies.com
NRX-100/NRX-101 (cycloserine/lurasidone)	NeuroRx Wilmington, DE	bipolar depression in patients with acute suicidal ideation and behavior (Fast Track)	Phase II/III www.neurorxpharma.com

Bipolar Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Rykindo® risperidone extended-release microsphere for injection (LY03004)	Luye Pharma Princeton, NJ	bipolar disorder	application submitted www.luye.cn
SAGE-217 (GABA A receptor modulator)	Sage Therapeutics Cambridge, MA	bipolar depression	Phase II www.sagerx.com
SEP-4199	Sunovion Pharmaceuticals Marlborough, MA	bipolar 1 depression	Phase II www.sunovion.com
SEP-378608	Sunovion Pharmaceuticals Marlborough, MA	bipolar disorder	Phase I www.sunovion.com
SKL-PSY/FZ-016 (serotonin 1A receptor agonist)	SK Life Science Paramus, NJ	bipolar disorder	Phase I www.sklifescienceinc.com
SPN-604 (sodium channel blocker)	Supernus Pharmaceuticals Rockville, MD	bipolar disorder	Phase II www.supernus.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AGN-241751 (NMDA receptor modulator)	Allergan Madison, NJ	major depressive disorder (Fast Track)	Phase II www.allergan.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AV-101 (NMDA receptor glycine B antagonist)	VistaGen Therapeutics South San Francisco, CA	major depressive disorder (Fast Track), major depressive disorder (post-ketamine or esketamine)	Phase II www.vistagen.com
		suicidal ideation	Phase I www.vistagen.com
AXS-05 (bupropion/dextromethorphan fixed-dose combination)	Axsome Therapeutics New York, NY	treatment resistant depression (Fast Track)	Phase III www.axsome.com
		major depressive disorder (Breakthrough Therapy)	Phase II www.axsome.com
BI-1358894 (TRPC4 channel inhibitor)	Boehringer Ingelheim Ridgefield, CT	major depressive disorder	Phase I www.boehringer-ingelheim.com
BTRX-335140 (opioid kappa receptor antagonist)	BlackThorn Therapeutics San Francisco, CA	mood disorders	Phase I www.blackthornrx.com
Fetzima [®] levomilnacipran extended release	Allergan Madison, NJ	major depressive disorder (pediatric)	Phase III www.allergan.com
FKB01MD (serotonin reuptake inhibition, serotonin 2/1A receptor agonism, serotonin 1D receptor modulation)	Fabre-Kramer Pharmaceuticals Houston, TX	major depressive disorder	Phase II www.fabrekramer.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ganaxolone (GABA A receptor agonist)	Marinus Pharmaceuticals Radnor, PA	postpartum depression	Phase II www.marinuspharma.com
JNJ-54175446 (purinergic P2X7 receptor antagonist)	Janssen Research & Development Raritan, NJ	major depressive disorder	Phase I www.janssen.com
JNJ 67953964 (opioid kappa receptor antagonist)	Janssen Research & Development Raritan, NJ	major depressive disorder	Phase II www.janssen.com
liafensine (DB104) (norepinephrine, dopamine, serotonin reuptake inhibitor)	Denovo Biopharma San Diego, CA	depression	Phase I completed www.denovobiopharma.com
lumateperone (ITI-007) (serotonin receptor antagonist, serotonin reuptake inhibitor, DPP modulator, glutamate receptor modulator)	Intra-Cellular Therapies New York, NY	major depressive disorder	Phase I www.intracellulartherapies.com
LY03005 (ansofaxine hydrochloride extended release)	Luye Pharma Princeton, NJ	moderate to severe depression	Phase III www.luye.cn
MIJ821 (NMDA negative allosteric modulator)	Novartis Pharmaceuticals East Hanover, NJ	treatment-resistant depression	Phase II www.novartis.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
MIN-117 (alpha7 adrenergic receptor modulator, serotonin1A/2A receptor antagonist, serotonin uptake inhibitor)	Minerva Neurosciences Waltham, MA	major depressive disorder	Phase II www.minervaneurosciences.com
NSI-189 (benzylpiperazine-aminopyridine neurogenic)	Neuralstem Germantown, MD	major depressive disorder	Phase II www.neuralstem.com
Nuplazid® pimavanserin	ACADIA Pharmaceuticals San Diego, CA	major depressive disorder (adjunctive therapy)	Phase III www.acadia-pharm.com
NV-5138 (MTORC1 protein stimulant)	Navitor Pharmaceuticals Cambridge, MA	major depressive disorder, treatment resistant depression	Phase I www.navitorpharma.com
PDC-1421 (NET inhibitor)	BioLite Taipei, Taiwan	major depressive disorder	Phase II www.biolite.com
PH10 nasal spray (chemoreceptor cell stimulant)	VistaGen Therapeutics South San Francisco, CA	major depressive disorder	Phase II www.vistagen.com
pramipexole (dopamine D2/D3 receptor agonist)	Chase Therapeutics Washington, DC	major depressive disorder	Phase II www.chasetherapeutics.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
REL-1017 (dextromethadone)	Relmada Therapeutics New York, NY	major depressive disorder (Fast Track)	Phase II www.relmada.com
SAGE-217 (GABA A receptor modulator)	Sage Therapeutics Cambridge, MA	major depressive disorder (Fast Track), postpartum depression	Phase III www.sagerx.com
scopolamine intranasal (muscarinic receptor antagonist)	Repurposed Therapeutics Tampa, FL	major depressive disorder	Phase I
seltorexant (MN-202) (orexin receptor type 2 antagonist)	Janssen Research & Development Raritan, NJ Minerva Neurosciences Waltham, MA	major depressive disorder	Phase II completed www.janssen.com www.minervaneurosciences.com
SEP-378614	Sunovion Pharmaceuticals Marlborough, MA	treatment resistant depression	Phase I www.sunovion.com
SHX-001 (ketamine transdermal patch)	Shenox Pharmaceuticals McLean, VA	major depressive disorder	Phase I www.shenoxpharma.com
sirukumab (interleukin 6 inhibitor)	Janssen Research & Development Raritan, NJ	major depressive disorder	Phase II completed www.janssen.com
SPN-809 (adrenergic reuptake inhibitor)	Supernus Pharmaceuticals Rockville, MD	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 at imminent risk for suicide	Phase III www.janssen.com
		major depressive disorder (pediatric)	Phase II www.janssen.com
Strada [™] ademetonine	MSI Methylation Sciences Burnaby, Canada	major depressive disorder	Phase II www.methylationsciences.com
SUVN 911 (alpha4beta2 nicotinic receptor antagonist)	Suven Life Sciences Monmouth Junction, NJ	major depressive disorder	Phase I www.suven.com
TAK-653 (AMPA receptor modulator)	Takeda Deerfield, IL	treatment-resistant depression	Phase I www.takeda.com
Travivo [™] gepirone ER	Fabre-Kramer Pharmaceuticals Houston, TX	major depressive disorder	application submitted www.fabrekramer.com
Trintellix [™] vortioxetine	Lundbeck Deerfield, IL Takeda Deerfield, IL	major depressive disorder (pediatric)	Phase III www.lundbeck.com www.takeda.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
TS-121	Taisho Pharmaceutical Tokyo, Japan	major depressive disorder	Phase II www.taisho.co.jp
TS-161	Taisho Pharmaceutical Tokyo, Japan	depression	Phase I www.taisho.co.jp
Viibryd® vilazodone	Allergan Madison, NJ	major depressive disorder (pediatric)	Phase III completed www.allergan.com
Vraylar® cariprazine	Allergan Madison, NJ	major depressive disorder (adjunctive therapy)	Phase III www.allergan.com
Zulresso® brexanolone	Sage Therapeutics Cambridge, MA	postpartum depression (adolescents)	Phase III www.sagerx.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Abilify Maintena® aripiprazole once-monthly	Lundbeck Deerfield, IL Otsuka Rockville, MD	schizophrenia (2 month treatment)	Phase I www.lundbeck.com www.otsuka.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ALKS 3831 (olanzapine/samidorphan)	Alkermes Waltham, MA	schizophrenia	Phase III www.alkermes.com
ASP4345 (dopamine D1 receptor modulator)	Astellas Pharma US Northbrook, IL	cognitive impairment associated with schizophrenia (CIAS)	Phase II www.astellas.com
AVN 211 (serotonin 6 receptor antagonist)	Avineuro Pharmaceuticals Hallandale Beach, FL	schizophrenia	Phase II/III www.avineuro.com
AVP-786 (deudextromethorphan analogue/ quinidine)	Avanir Pharmaceuticals Aliso Viejo, CA Concert Pharmaceuticals Lexington, MA	schizophrenia (negative symptoms)	Phase II www.avanir.com www.concertpharma.com
basmisanil (GABA A alpha 5 receptor modulator)	Roche Basel, Switzerland	CIAS	Phase II www.roche.com
BI 409306 (PDE9A inhibitor)	Boehringer Ingelheim Ridgefield, CT	attenuated psychosis syndrome, schizophrenia, psychotic disorders (pediatric)	Phase II www.boehringer-ingelheim.com
BI 425809 (glycine transporter 1 inhibitor)	Boehringer Ingelheim Ridgefield, CT	schizophrenia (combination with Computerized Cognitive Training)	Phase II www.boehringer-ingelheim.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
BIIB104 (AMPA receptor modulator)	Biogen Cambridge, MA	CIAS (Fast Track)	Phase II www.biogen.com
CTP-692 (deuterated D-serine)	Concert Pharmaceuticals Lexington, MA	schizophrenia	Phase I www.concertpharma.com
CVN058	Cerevance Boston, MA	CIAS	Phase I www.cerevance.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 www.delpor.com
DSP-6745 (serotonin 5-HT _{2A/c} receptors dual antagonist)	Sunovion Pharmaceuticals Marlborough, MA	psychosis in Parkinson's disease	Phase I www.sunovion.com
evenamide (voltage-gated sodium channel blocker)	Newron Pharmaceuticals Morristown, NJ	schizophrenia	Phase II www.newron.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
FKF02SC (dopamine D2/D3 receptor antagonist, serotonin 2C/2A receptor antagonist, alpha-1 adrenergic receptor antagonist)	Fabre-Kramer Pharmaceuticals Houston, TX	schizophrenia	Phase II www.fabrekramer.com
HP-3070 (asenapine transdermal)	Hisamitsu Pharmaceutical Tosu, Japan Noven Pharmaceuticals Miami, FL	schizophrenia	application submitted www.global.hisamitsu www.noven.com
KarXT (muscarinic M1/M4 receptor agonist, muscarinic receptor antagonist)	Karuna Pharmaceuticals Boston, MA	psychosis in schizophrenia	Phase II www.karunatx.com
Lu AF11167 (PDE10A inhibitor)	Lundbeck Deerfield, IL	schizophrenia (negative symptoms)	Phase II www.lundbeck.com
lumateperone (ITI-007) (serotonin receptor antagonist, serotonin reuptake inhibitor, DPP modulator, glutamate receptor modulator)	Intra-Cellular Therapies New York, NY	schizophrenia (Fast Track)	application submitted www.intracellulartherapies.com
LY03010 (paliperidone palmitate)	Luye Pharma Princeton, NJ	schizophrenia, schizoaffective disorder	Phase I www.luye.cn

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
MK-8189	Merck Kenilworth, NJ	schizophrenia	Phase II www.merck.com
NaBen® sodium benzoate ORPAHN DRUG	SyneuRx New Taipei City, Taiwan	schizophrenia (adolescent), schizophrenia (adult), refractory schizophrenia	Phase II/III www.syneurx.com
Nuplazid® pimavanserin	ACADIA Pharmaceuticals San Diego, CA	dementia-related psychosis, schizophrenia inadequate response (adjunctive therapy)	Phase III www.acadia-pharm.com
		schizophrenia (negative symptoms) (adjunctive therapy)	Phase II www.acadia-pharm.com
paliperidone palmitate 6-month long-acting injection	Janssen Pharmaceutical Raritan, NJ	schizophrenia	Phase III www.janssen.com
Rexulti® brexpiprazole	Lundbeck Deerfield, IL Otsuka Pharmaceutical Rockville, MD	schizophrenia (adolescents) (oral)	Phase III www.lundbeck.com www.otsuka.com
		schizophrenia (depot injection)	Phase I www.lundbeck.com www.otsuka.com

Schizophrenia

Product Name

Sponsor

Indication

Development Phase

RG7906
(RO6889450)

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

Phase III
www.rovi.es

roluperidone (MIN-101)
(serotonin 2A receptor antagonist,
sigma-2 receptor antagonist)

Minerva Neurosciences
Waltham, MA

schizophrenia

Phase III
www.minervaneurosciences.com

RP5063
(dopamine D2/D3/D4 receptor
partial agonist, serotonin 1A/2A
receptor partial agonist, serotonin
2B/6/7 receptor antagonist)

Reviva Pharmaceuticals
Cupertino, CA

schizophrenia

Phase II
www.revivapharma.com

Rykindo®
risperidone extended-release
microsphere for injection
(LY03004)

Luye Pharma
Princeton, NJ

schizophrenia

application submitted
www.luye.cn

SEP-363856
(serotonin 1A receptor agonist,
trace amine-associated receptor 1
agonist)

Sunovion Pharmaceuticals
Marlborough, MA

schizophrenia (Breakthrough Therapy)

Phase III
www.sunovion.com

psychosis in Parkinson's disease

Phase II
www.sunovion.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SKL20540 (alpha7 nicotinic acetylcholine receptor agonist)	SK Life Science Paramus, NJ	CIAS	Phase I www.sklifescienceinc.com
TAK-041 (GPR139 agonist)	Takeda Deerfield, IL	CIAS (negative symptoms)	Phase I www.takeda.com
TAK-831 (DAAO inhibitor)	Takeda Deerfield, IL	CIAS (negative symptoms)	Phase II www.takeda.com
TS-134	Taisho Pharmaceutical Tokyo, Japan	schizophrenia	Phase I www.taisho.co.jp
TV-46000 (risperidone LAI)	Teva North America Parsippany, NJ	schizophrenia	Phase III www.tevapharm.com
Vraylar® cariprazine	Allergan Madison, NJ	schizophrenia relapse prevention, schizophrenia (adolescents)	Phase III www.allergan.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AD04 (ondansetron)	ADial Pharmaceuticals Charlottesville, VA	alcohol use disorder	Phase II www.adialpharma.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AEF0117 (CB1 receptor antagonist)	Aelis Farma Bordeaux, France	marijuana use disorder	Phase II www.aelisfarma.com
ANS-6637 (ALDH 2 inhibitor)	Amygdala Neurosciences Palo Alto, CA	alcohol use disorder, opioid use disorder	Phase I www.amygns.com
APC-6000 (naloxone injection)	Adamis Pharmaceuticals San Diego, CA	opioid use disorder	application submitted www.adamispharmaceuticals.com
arbaclofen ER	Osmotica Pharmaceuticals Bridgewater, NJ	opioid use disorder	Phase I www.osmotica.com
ASP-8062 (GABA-B receptor modulator)	Astellas Pharma US Northbrook, IL	drug use disorder	Phase I www.astellas.com
AXS-05 (bupropion/dextromethorphan fixed-dose combination)	Axsome Therapeutics New York, NY	tobacco use disorder	Phase II www.axsome.com
buprenorphine/naloxone sublingual spray	INSYS Therapeutics Chandler, AZ	opioid use disorder	Phase I www.insysrx.com
CERC-501 (opioid kappa receptor antagonist)	Janssen Research & Development Raritan, NJ	tobacco use disorder	Phase II completed www.janssen.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
cytisinicline (alpha4 beta2 nicotinic receptor agonist)	Achieve Life Sciences Seattle, WA	tobacco use disorder	Phase III www.achievelifesciences.com
EMB-001 (metyrapone/oxazepam)	Embera NeuroTherapeutics Boston, MA	cocaine use disorder, tobacco use disorder	Phase I www.emberaneuro.com
GET73 (metabotropic glutamate receptor 5 antagonist)	CT Laboratories Sanremo, Italy	alcohol use disorder	Phase II www.labct.it/en/
IXT-m200 (chimeric mAb)	InterveXion Therapeutics Little Rock, AR	methamphetamine use disorder (Fast Track)	Phase I/II www.intervexion.com
MDL-001 (naloxone buccal gel)	Mucodel Greensboro, NC	opioid use disorder	Phase I completed www.nasobain.com
MN-166 (ibudilast)	MediciNova La Jolla, CA National Institute on Drug Abuse Rockville, MD	alcohol use disorder, methamphetamine use disorder (Fast Track)	Phase II www.medicinova.com
nalmefene HCl	Purdue Pharma Stamford, CT	opioid use disorder (Fast Track)	Phase I www.purduepharma.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
naloxone nasal spray	Hikma Pharmaceuticals London, United Kingdom	opioid use disorder (overdose)	application submitted www.insysrx.com
nicotine transmucosal	Bionex Pharmaceuticals North Brunswick, NJ	tobacco use disorder	in clinical trials www.bionexpharma.com
NS2359 (triple monoamine reuptake inhibitor)	Saniona Ballerup, Denmark University of Pennsylvania Philadelphia, PA	cocaine use disorder	Phase II www.saniona.com
OMS405 (PPAR gamma agonist)	Omeros Seattle, WA	opioid use disorder, tobacco use disorder	Phase II www.omeros.com
OMS527 (PDE7 inhibitor)	Omeros Seattle, WA	drug use disorder	Phase I www.omeros.com
OPNT002 (opioid antagonist 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	Phase I www.opiant.com
PT-150 (glucocorticoid receptor antagonist)	Pop Test Cortisol Cliffside Park, NJ	alcohol use disorder	Phase I

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
REL-1028 (BuTab) (oral buprenorphine)	Relmada Therapeutics New York, NY	opioid use disorder	Phase I completed www.relmada.com
TNX-1300 (double mutant cocaine esterase)	Tonix Pharmaceuticals New York, NY	cocaine use disorder (Breakthrough Therapy)	Phase II www.tonixpharma.com
X-22 (nicotinic receptor agonist)	22nd Century Williamsville, NY	tobacco use disorder	Phase II www.xxiicentury.com

Other Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AR20	Arbor Pharmaceuticals Atlanta, GA	mental disorders (pediatric)	Phase I www.arborpharma.com
AR33	Arbor Pharmaceuticals Atlanta, GA	mental disorders (pediatric)	Phase II www.arborpharma.com
AVP-786 (deudextromethorphan analogue/ quinidine)	Avanir Pharmaceuticals Aliso Viejo, CA Concert Pharmaceuticals Lexington, MA	disinhibition syndrome in neuro- degenerative disorders, intermittent explosive disorder	Phase II www.avanir.com www.concertpharma.com

Other Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
dasotraline (SEP-225289) (serotonin, norepinephrine and dopamine reuptake inhibitor)	Sunovion Pharmaceuticals Marlborough, MA	binge eating disorder (adult)	Phase III www.sunovion.com
FKW00GA (serotonin 1A receptor agonist, serotonin 2A receptor antagonist)	Fabre-Kramer Pharmaceuticals Houston, TX	sexual dysfunction	Phase II www.fabrekramer.com
Rexulti® brexpiprazole (oral)	Lundbeck Deerfield, IL Otsuka Pharmaceutical Rockville, MD	borderline personality disorder	Phase II www.lundbeck.com www.otsuka.com
SRX246 (vasopressin 1a receptor antagonist)	Azevan Pharmaceuticals Bethlehem, PA	intermittent explosive disorder	Phase II completed www.azevan.com
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
Travivo™ gepirone ER	Fabre-Kramer Pharmaceuticals Houston, TX	hypoactive sexual desire disorder	Phase II www.fabrekramer.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 **August 26, 2019**. 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.

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.