

2016 Medicines in Development for Mental Health

Anxiety Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
7-oxoprasterone (At-Ease)	Humanetics <i>Edina, MN</i>	post-traumatic stress disorder (PTSD)	Phase II www.humaneticscorp.com
aloradine (sensory receptor cell modulator)	Pherin Pharmaceuticals <i>Los Altos, CA</i>	social phobia	Phase III www.pherin.com
AVN 101 (serotonin 6 receptor antagonist)	AllaChem <i>Hallandale Beach, FL</i> Avineuro Pharmaceuticals <i>San Diego, CA</i>	anxiety	Phase II www.allachem.com www.avineuro.com
AVP-786 (dextromethorphan analogue/ quinidine)	Avanir Pharmaceuticals <i>Aliso Viejo, CA</i> Concert Pharmaceuticals <i>Lexington, MA</i>	agitation in Alzheimer's disease (Fast Track) <i>(see also depression, schizophrenia)</i>	Phase III www.avanir.com www.concertpharma.com
AVP-923 (dextromethorphan/quinidine fixed-dose combination)	Avanir Pharmaceuticals <i>San Diego, CA</i>	agitation in Alzheimer's disease	Phase II www.avanir.com
AXS-05 (bupropion/dextromethorphan fixed-dose combination)	Axsome Therapeutics <i>New York, NY</i>	agitation in Alzheimer's disease <i>(see also depression)</i>	Phase I www.axsome.com
EDG004 (lorazepam extended release)	Edgemont Pharmaceuticals <i>Austin, TX</i>	generalized anxiety disorder	Phase III www.edgemontpharma.com

Anxiety Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ELND005 (amyloid beta-protein inhibitor)	Transition Therapeutics <i>Toronto, Canada</i>	agitation/aggression in Alzheimer's disease (Fast Track)	Phase II/III www.transitiontherapeutics.com
Nuedexta® dextromethorphan and quinidine	Avanir Pharmaceuticals <i>Aliso Viejo, CA</i>	agitation in Alzheimer's disease	Phase II www.avinar.com
Rexulti® brexpiprazole	Otsuka Pharmaceutical <i>Rockville, MD</i>	agitation in Alzheimer's disease, PTSD (see also schizophrenia)	Phase III www.otsuka.com
SNC-102 (acamprosate controlled-release)	Synchroneuron <i>Newton, MA</i>	combat-related PTSD	Phase I www.synchroneuron.com
TGFK08AA (serotonin 1A receptor modulator)	Fabre-Kramer Pharmaceuticals <i>Houston, TX</i>	generalized anxiety disorder	Phase II www.fabrekramer.com
TGW00AA (serotonin receptor agonist)	Fabre-Kramer Pharmaceuticals <i>Houston, TX</i>	generalized anxiety disorder, social phobia	Phase II www.fabrekramer.com
TNX-102 SL (cyclobenzaprine very low dose)	Tonix Pharmaceuticals <i>New York, NY</i>	PTSD	Phase II www.tonixpharma.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ADD-OC1	PharmaLogika <i>Raleigh, NC</i>	attention-deficit/hyperactivity disorder (ADHD)	Phase II www.pharmalogika.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ATS (dexamfetamine transdermal)	Noven Pharmaceuticals <i>Miami, FL</i>	ADHD	Phase II www.noven.com
Brintellix [®] vortioxetine	Lundbeck <i>Deerfield, IL</i> Takeda <i>Deerfield, IL</i>	ADHD (adult)	Phase II www.lundbeck.com www.takeda.com
centanafadine (triple reuptake inhibitor)	Neurovance <i>Cambridge, MA</i>	ADHD (adult)	Phase II www.neurovance.com
dasotraline (triple reuptake inhibitor)	Sunovion Pharmaceuticals <i>Marlborough, MA</i>	ADHD (adult and pediatric) <i>(see also eating disorders)</i>	Phase III www.sunovion.com
eltoprazine (serotonin 1A/1B partial agonist)	Amarantus Bioscience <i>San Francisco, CA</i>	ADHD (adult)	Phase III www.amarantus.com
HLD200 (methylphenidate modified release)	Highland Therapeutics <i>Toronto, Canada</i> Ironshore Pharmaceuticals & Development <i>Toronto, Canada</i>	ADHD (pediatric)	Phase III www.highlandtherapeutics.com
metadoxine extended release	Alcobra <i>Tel-Aviv, Israel</i>	ADHD (adult)	Phase III www.alcobra-pharma.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ORADUR®-Methylphenidate methylphenidate sustained release	DURECT <i>Cupertino, CA</i> Orient Pharma <i>Taipei, Taiwan</i>	ADHD	Phase III www.durect.com
NFC-1 (mGluR neuromodulator)	Medgenics <i>Philadelphia, PA</i>	mGlu network mutation positive ADHD	Phase I www.medgenics.com
NLS-1 (mazindol)	NeuroLifeSciences <i>Paris, France</i>	ADHD	Phase II www.neurolifesciences.com
NT0102 (methylphenidate extended release)	Neos Therapeutics <i>Grand Prairie, TX</i>	ADHD (pediatric)	application submitted www.neostx.com
NT0201 (amphetamine extended-release)	Neos Therapeutics <i>Grand Prairie, TX</i>	ADHD	in clinical trials www.neostx.com
RP5063 (partial agonist of dopamine and serotonin)	Reviva Pharmaceuticals <i>Santa Clara, CA</i>	ADHD/attention-deficit disorder <i>(see also bipolar, depression, schizophrenia)</i>	Phase I www.revivapharma.com
SHP465 (adrenergic receptor agonist)	Shire <i>Lexington, MA</i>	ADHD	Phase III www.shire.com
SKL-ADHD (adrenergic and dopamine uptake inhibitor)	SK Biopharmaceuticals <i>Fair Lawn, NJ</i>	ADHD	Phase I www.skbp.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SPN-810 (molindone)	Supernus Pharmaceuticals <i>Rockville, MD</i>	impulse aggression in ADHD	Phase II completed www.supernus.com
SPN-812 (adrenergic uptake inhibitor)	Supernus Pharmaceuticals <i>Rockville, MD</i>	ADHD	Phase II completed www.supernus.com
TRI-102	Tris Pharma <i>Monmouth Junction, NJ</i>	ADHD	Phase III www.trispharma.com

Bipolar Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Abilify® Maintena® aripiprazole for extended release injectable suspension (depot injection)	Otsuka Pharmaceutical <i>Rockville, MD</i>	bipolar disorder (maintenance treatment)	Phase III www.otsuka.com
Cyclurad™ (cycloserine/lurasidone)	NeuroRx <i>Wilmington, DE</i>	acute suicidal crisis associated with bipolar depression	Phase II completed www.neurorxpharma.com
Geodon® ziprasidone	Pfizer <i>New York, NY</i>	bipolar 1 disorder (pediatric)	Phase III www.pfizer.com
ITI-007 (serotonin receptor antagonist)	Intra-Cellular Therapies <i>New York, NY</i>	bipolar depression (see also schizophrenia)	Phase III www.intracellulartherapies.com
JNJ-18038683 (serotonin receptor antagonist)	Janssen Research & Development <i>Raritan, NJ</i>	bipolar disorder	Phase II www.janssenrnd.com

Bipolar Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Latuda® lurasidone	Sunovion Pharmaceuticals <i>Marlborough, MA</i>	bipolar 1 depression (pediatric) <i>(see also schizophrenia)</i>	Phase III www.sunovion.com
RP5063 (partial agonist of dopamine and serotonin)	Reviva Pharmaceuticals <i>Santa Clara, CA</i>	bipolar disorder <i>(see also ADHD, depression, schizophrenia)</i>	Phase I www.revivapharma.com
SKL-PSY/FZ-016 (serotonin 1A receptor agonist)	SK Biopharmaceuticals <i>Fair Lawn, NJ</i>	bipolar disorder	Phase I www.skbp.com
YKP3089 (cenobamate)	SK biopharmaceuticals <i>Fair Lawn, NJ</i>	bipolar disorder	Phase II www.skbp.com
Vraylar™ cariprazine	Allergan <i>Parsippany, NJ</i>	bipolar 1 depression <i>(see also depression)</i>	Phase II www.allergan.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ALKS 5461 (buprenorphine/samidorphan fixed-dose combination)	Alkermes <i>Waltham, MA</i>	major depressive disorder (Fast Track)	Phase III www.alkermes.com
AV-101 (NMDA receptor antagonist)	VistaGen Therapeutics <i>South San Francisco, CA</i> National Institutes of Health <i>Bethesda, MA</i>	major depressive disorder	Phase II www.vistagen.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AVP-786 (deuterated dextromethorphan/ quinidine)	Avanir Pharmaceuticals <i>Aliso Viejo, CA</i> Concert Pharmaceuticals <i>Lexington, MA</i>	depression <i>(see also anxiety, schizophrenia)</i>	Phase II www.avinar.com www.concertpharma.com
AXS-05 (bupropion/dextromethorphan fixed-dose combination)	Axsome Therapeutics <i>New York, NY</i>	treatment-resistant depression <i>(see also anxiety)</i>	Phase III www.axsome.com
basimglurant (mGluR5 antagonist)	Roche <i>Basel, Switzerland</i>	treatment-resistant depression	Phase II www.roche.com
Botox [®] onabotulinumtoxinA	Allergan <i>Parsippany, NJ</i>	major depressive disorder	Phase II www.allergan.com
CERC-301 (NR2B specific NMDA antagonist)	Cerecor <i>Baltimore, MD</i>	major depressive disorder (Fast Track) (adjunctive treatment)	Phase II www.cerecor.com
CERC-501 (KOR antagonist)	Cerecor <i>Baltimore, MD</i>	major depressive disorder (adjunctive treatment) <i>(see also substance abuse)</i>	Phase II www.cerecor.com
esketamine (intranasal) (NMDA receptor antagonist)	Janssen Research & Development <i>Raritan, NJ</i>	treatment-resistant depression (Fast Track)	Phase III www.janssenrnd.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
EVT 101 (NR2B NMDA receptor antagonist)	Evotec <i>Hamburg, Germany</i> Janssen Research & Development <i>Raritan, NJ</i>	major depressive disorder	Phase I www.janssenrnd.com
EVT 103 (NR2B NMDA receptor antagonist)	Evotec <i>Hamburg, Germany</i> Janssen Research & Development <i>Raritan, NJ</i>	major depressive disorder	Phase I www.janssenrnd.com
gepirone ER	Fabre-Kramer Pharmaceuticals <i>Houston, TX</i>	major depressive disorder	application submitted www.fabrekramer.com
JNJ-39393406 (alpha7 nicotinic acetylcholine receptor modulator)	Janssen Research & Development <i>Raritan, NJ</i>	depressive disorders	Phase II www.janssenrnd.com
JNJ-42847922 (orexin receptor type 2 antagonists)	Janssen Research & Development <i>Raritan, NJ</i>	major depressive disorder	Phase I completed www.janssenrnd.com
LY03005 (dual uptake inhibitor)	Luye Pharma Group <i>Shanghai, China</i>	major depressive disorder	Phase I www.luye.cn
MIN-117 (serotonin receptor antagonist/serotonin and dopamine reuptake inhibitor)	Minerva Neurosciences <i>Waltham, MA</i>	major depressive disorder	Phase II www.minervaneurosciences.com
NRX-1074 (NMDA receptor agonist)	Naurex <i>Evanston, IL</i>	major depressive disorder	Phase II www.naurex.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NSI-189 (stimulating neurogenesis)	Neuralstem <i>Germantown, MD</i>	major depressive disorder	Phase I www.neuralstem.com
PH10 nasal spray (chemoreceptor cell modulator)	Pherin Pharmaceuticals <i>Los Altos, CA</i>	major depressive disorder	Phase II www.pherin.com
Pristiq [®] desvenlafaxine	Pfizer <i>New York, NY</i>	major depressive disorder (children and adolescents)	Phase III www.pfizer.com
rapastinel (NMDA receptor agonist)	Allergan <i>Parsippany, NJ</i>	major depressive disorder	Phase II www.allergan.com
RP5063 (partial agonist of dopamine and serotonin)	Reviva Pharmaceuticals <i>Santa Clara, CA</i>	major depressive disorder (see also ADHD, bipolar, schizophrenia)	Phase I www.revivapharma.com
SAGE-547 (GABA A receptor modulator)	Sage Therapeutics <i>Cambridge, MA</i>	postpartum depression	Phase II www.sagerx.com
sirukumab	Janssen Research & Development <i>Raritan, NJ</i>	major depressive disorder	Phase II www.janssenrnd.com
Strada [™] ademetonine new oral formulation	MSI Methylation Sciences <i>Burnaby, Canada</i>	major depressive disorder (adjunctive treatment)	Phase II www.methylationsciences.com
TGBA01AD (serotonin receptor agonist, serotonin receptor modulator, serotonin uptake inhibitor)	Fabre-Kramer Pharmaceuticals <i>Houston, TX</i>	major depressive disorder	Phase II www.fabrekramer.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
TS-121	Taisho Pharmaceutical R&D <i>Morristown, NJ</i>	depression	Phase I www.taisho.co.jp
Viibryd [®] vilazodone	Allergan <i>Parsippany, NJ</i>	major depressive disorder (pediatric)	Phase III www.allergan.com
Vraylar [™] cariprazine	Allergan <i>Parsippany, NJ</i>	major depressive disorder (adjunctive treatment) <i>(see also bipolar)</i>	Phase III www.allergan.com

Eating Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
dasotraline (triple reuptake inhibitor)	Sunovion Pharmaceuticals <i>Marlborough, MA</i>	binge eating disorder <i>(see also ADHD)</i>	Phase II www.sunovion.com
naloxone nasal spray	Opiant Pharmaceuticals <i>Santa Monica, CA</i>	binge eating disorder <i>(see also substance use)</i>	Phase II www.opiant.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ALKS 3831 (olanzapine/samidorphan (fixed-dose combination))	Alkermes <i>Waltham, MA</i>	schizophrenia <i>(see also substance use)</i>	Phase III www.alkermes.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AMG 581	Amgen <i>Thousand Oaks, CA</i>	schizophrenia	Phase I www.amgen.com
APN1125 (alpha7 nicotinic acetylcholine receptor agonist)	Alpharmagen <i>South San Francisco, CA</i> CoMentis <i>San Francisco, CA</i>	schizophrenia	Phase I www.comentis.com
Aristada [®] aripiprazole lauroxil	Alkermes <i>Waltham, MA</i>	schizophrenia (extended durations)	Phase III www.alkermes.com
Atx11-004	Aestus Therapeutics <i>East Windsor, NJ</i>	schizophrenia	Phase I www.aestustherapeutics.com
AVN 211 (serotonin 6 receptor antagonist)	AllaChem <i>Hallandale Beach, FL</i> Avineuro Pharmaceuticals <i>San Diego, CA</i>	schizophrenia	Phase II/III www.allachem.com www.avineuro.com
AVP-786 (deuterated dextromethorphan/ quinidine)	Avanir Pharmaceuticals <i>Aliso Viejo, CA</i> Concert Pharmaceuticals <i>Lexington, MA</i>	schizophrenia <i>(see also anxiety, depression)</i>	Phase II www.avinar.com www.concertpharma.com
BI-409306 (PDE9A inhibitor)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	schizophrenia	Phase II www.boehringer-ingelheim.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
DSP-3748 (alpha7 nicotinic acetylcholine receptor agonist)	Sunovion Pharmaceuticals <i>Marlborough, MA</i>	cognitive impairment associated with schizophrenia (CIAS)	Phase I www.sunovion.com
encenicline (alpha-7 agonist)	Forum Pharmaceuticals <i>Waltham, MA</i>	CIAS	Phase III www.forumpharma.com
Fanapt® iloperidone	Vanda Pharmaceuticals <i>Washington, DC</i>	schizophrenia (maintenance treatment)	application submitted www.vandapharmaceuticals.com
FRM-6308 (PDE 10 inhibitor)	Forum Pharmaceuticals <i>Waltham, MA</i>	schizophrenia	Phase I www.forumpharma.com
HP-3070 (asenapine transdermal)	Hisamitsu Pharmaceutical <i>Saga, Japan</i> Noven Pharmaceuticals <i>Miami, FL</i>	schizophrenia	Phase I www.hisamitsu.co.jp www.noven.com
ITI-007 (serotonin receptor antagonist)	Intra-Cellular Therapies <i>New York, NY</i>	schizophrenia (see also bipolar)	Phase III www.intracellulartherapies.com
Latuda® lurasidone	Sunovion Pharmaceuticals <i>Marlborough, MA</i>	pediatric schizophrenia (see also bipolar)	Phase III www.sunovion.com
Lu AF11167 (phosphoric diester hydrolase inhibitor)	Lundbeck <i>Deerfield, IL</i>	schizophrenia	Phase I www.lundbeck.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Lu AF35700 (dopamine D2 receptor modulator)	Lundbeck <i>Deerfield, IL</i>	schizophrenia	Phase III www.lundbeck.com
LY3004 (risperidone controlled release)	Luye Pharma Group <i>Shanghai, China</i>	schizophrenia, schizoaffective disorder	Phase I completed www.luye.cn
MIN-101 (serotonin 2A receptor antagonist/ sigma-2 receptor antagonist)	Minerva Neurosciences <i>Waltham, MA</i>	schizophrenia	Phase II www.minervaneurosciences.com
MK-8189	Merck <i>Kenilworth, NJ</i>	schizophrenia	Phase I completed www.merck.com
Nuplazid™ pimavanserin	ACADIA Pharmaceuticals <i>San Diego, CA</i>	Parkinson's disease psychosis	application submitted www.acadia-pharm.com
		Alzheimer's disease psychosis, schizophrenia	Phase II www.acadia-pharm.com
NW-3509 (potent sodium channel blocker)	Newron Pharmaceuticals <i>Bresso, Italy</i>	schizophrenia	Phase II www.newron.com
OMS824 (PDE 10 inhibitor)	Omeros <i>Seattle, WA</i>	schizophrenia	Phase II www.omeros.com
PF-04958242 (AMPA receptor modulator)	Pfizer <i>New York, NY</i>	schizophrenia	Phase I www.pfizer.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
PF-06266047	Pfizer <i>New York, NY</i>	schizophrenia	Phase I www.pfizer.com
PF-06412562	Pfizer <i>New York, NY</i>	CIAS	Phase I www.pfizer.com
pomaglumedad methionil (mGluR2/mGluR3 receptor agonist)	Eli Lilly <i>Indianapolis, IN</i>	schizophrenia	Phase I www.lilly.com
RBP-7000 (risperidone sustained release)	Indivior <i>Richmond, VA</i>	schizophrenia	Phase III www.indivior.com
Relday™ risperidone controlled release	DURECT <i>Cupertino, CA</i> Zogenix <i>San Diego, CA</i>	schizophrenia	Phase I www.durect.com www.zogenix.com
Rexulti® brexpiprazole	Otsuka Pharmaceutical <i>Rockville, MD</i>	schizophrenia (maintenance treatment) <i>(see also anxiety)</i>	application submitted www.otsuka.com
		schizophrenia (adolescents)	Phase I www.otsuka.com
risperidone controlled-release implant	Braeburn Pharmaceuticals <i>Princeton, NJ</i>	schizophrenia	Phase II www.braeburnpharmaceuticals.com
Risperidone ISM® risperidone extended release	Laboratorios Farmacéuticos Rovi <i>Madrid, Spain</i>	schizophrenia	Phase II completed www.rovi.es

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
RP5063 (partial agonist of dopamine and serotonin)	Reviva Pharmaceuticals <i>Santa Clara, CA</i>	schizophrenia <i>(see also ADHD, bipolar, depression)</i>	Phase II www.revivapharma.com
		Alzheimer's disease psychosis, Parkinson's disease psychosis	Phase I www.revivapharma.com
SEP-363856	Sunovion Pharmaceuticals <i>Marlborough, MA</i>	schizophrenia	Phase I www.sunovion.com
SKL-A4R (PDE10A inhibitor)	SK Biopharmaceuticals <i>Fair Lawn, NJ</i>	CIAS	Phase I www.skbp.com
TAK-058 (serotonin 3 receptor antagonist)	Takeda <i>Deerfield, IL</i>	schizophrenia, CAIS	Phase I www.takeda.com
TAK-063 (PDE10A inhibitor)	Takeda <i>Deerfield, IL</i>	schizophrenia	Phase II www.takeda.com
TAK-915 (PDE2A inhibitor)	Takeda <i>Deerfield, IL</i>	schizophrenia	Phase I www.takeda.com
TGOF02N (atypical antipsychotic)	Fabre-Kramer Pharmaceuticals <i>Houston, TX</i>	schizophrenia	Phase II www.fabrekramer.com
TS-134	Taisho Pharmaceutical R&D <i>Morristown, NJ</i>	schizophrenia	Phase I www.taisho.co.jp

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
18-MC (alpha-3/beta-4 nicotinic receptor antagonist)	Savant HWP <i>San Carlos, CA</i>	anti-addiction treatment	Phase I www.savanthwp.com
AD04 (serotonin-3 antagonist)	ADial Pharmaceuticals <i>Charlottesville, VA</i>	alcohol use disorder	Phase II www.adialpharma.com
ALKS 3831 (olanzapine/samidorphan fixed-dose combination)	Alkermes <i>Waltham, MA</i>	alcohol use disorder (see also schizophrenia)	Phase II www.alkermes.com
arbaclofen placarbil	Indivior <i>Richmond, VA</i>	alcohol use disorder	Phase II www.indivior.com
buprenorphine/naloxone sublingual spray	Insys Therapeutics <i>Chandler, AZ</i>	opioid use disorder (Fast Track)	Phase I www.insysrx.com
CAM2038q1w (buprenorphine once-weekly depot)	Braeburn Pharmaceuticals <i>Princeton, NJ</i> Camurus <i>Lund, Sweden</i>	opioid use disorder (Fast Track)	Phase III www.braeburnpharmaceuticals.com www.camurus.com
CAM2038q4w (buprenorphine once-monthly depot)	Braeburn Pharmaceuticals <i>Princeton, NJ</i> Camurus <i>Lund, Sweden</i>	opioid use disorder (Fast Track)	Phase III www.braeburnpharmaceuticals.com www.camurus.com
CERC-501 (selective KOR antagonist)	Cerecor <i>Baltimore, MD</i>	substance use disorders (see also depression)	Phase II www.cerecor.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
EMB-001 (metyrapone/oxazepam)	Embera NeuroTherapeutics <i>Sudbury, MA</i>	substance use disorder	Phase I completed www.emberaneuro.com
GET 73 (γ -hydroxybutyric acid analogue)	CT Laboratories (Laboratorio Farmaceutico CT) <i>Sanremo, Italy</i>	alcohol use disorder	Phase I/II www.labct.it/en/
Horizant gabapentin enacarbil	National Institute on Alcohol Abuse and Alcoholism <i>Bethesda, MD</i> XenoPort <i>Santa Clara, CA</i>	alcohol use disorder	Phase II www.xenoport.com
INV102 (nadolol)	Invion <i>Brisbane, Australia</i>	smoking withdrawal	Phase II completed www.inviongroup.com
IXT-m200 (METH-mAb)	InterVexion Therapeutics <i>Little Rock, AR</i>	methamphetamine use disorders (Fast Track)	Phase I www.intervexion.com
lofexidine (alpha 2 adrenergic receptor agonist)	US WorldMeds <i>Louisville, KY</i>	opioid use disorder	Phase III www.usworldmeds.com
MN-166 (ibudilast)	MediciNova <i>La Jolla, CA</i> National Institute on Alcohol Abuse and Alcoholism <i>Bethesda, MD</i> National Institute on Drug Abuse <i>Rockville, MD</i>	alcohol use disorder, methamphetamine use disorder, 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>
naloxone nasal spray	Indivior <i>Richmond, VA</i>	opioid use disorder (Fast Track)	application submitted www.indivion.com
naloxone nasal spray	Opiant Pharmaceuticals <i>Santa Monica, CA</i>	cocaine use disorder <i>(see also eating disorders)</i>	Phase II www.opiant.com
nicotine inhalation	Aradigm <i>Hayward, CA</i>	smoking withdrawal	Phase I www.aradigm.com
NS2359	Saniona <i>Ballerup, Denmark</i> University of Pennsylvania <i>Pittsburgh, PA</i>	cocaine use disorder	Phase II www.saniona.com
OMS405 (PPAR-gamma agonist)	Omeros <i>Seattle, WA</i>	opioid use disorder, smoking withdrawal	Phase II www.omeros.com
PF-05402536 (smoking cessation vaccine)	Pfizer <i>New York, NY</i>	smoking withdrawal	Phase I www.pfizer.com
Probuphine® buprenorphine implant	Braeburn Pharmaceuticals <i>Princeton, NJ</i> Titan Pharmaceuticals <i>South San Francisco, CA</i>	opioid use disorder	application submitted www.braeburnpharmaceuticals.com www.titanpharm.com
QuitPak® bupropion/mecamylamine	Cary Pharmaceuticals <i>Great Falls, VA</i>	smoking withdrawal	Phase I completed www.carypharma.com
RBP-6000 (buprenorphine one-month depot)	Indivior <i>Richmond, VA</i>	opioid use disorder	Phase III www.indivior.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
RBP-6300 (buprenorphine/naloxone swallowable tablet)	Indivior <i>Richmond, VA</i>	opioid use disorder	Phase III www.indivior.com
RBP-8000 (cocaine esterase)	Indivior <i>Richmond, VA</i>	cocaine use disorder	Phase II www.indivior.com
REL-1028 (oral buprenorphine)	Relmada Therapeutics <i>New York, NY</i>	opioid use disorder	Phase I www.relmada.com
X-22 (very low-dose nicotine)	22nd Century <i>Westport, CT</i>	smoking withdrawal	Phase II www.xxiicentury.com

Other Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AR19	Arbor Pharmaceuticals <i>Atlanta, GA</i>	mental disorders (pediatric)	Phase III www.arborpharma.com
AR20	Arbor Pharmaceuticals <i>Atlanta, GA</i>	mental disorders (pediatric)	Phase II www.arborpharma.com
BHV-4157	Biohaven Pharmaceuticals <i>British Virgin Islands</i>	mental disorders	in clinical trials
edivoxetine (adrenergic uptake inhibitors)	Eli Lilly <i>Indianapolis, IN</i>	mental disorders	Phase II www.lilly.com

Other Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
KPAX002 (methylphenidate)	K-PAX Pharmaceuticals <i>Mill Valley, CA</i>	Gulf War illness	Phase II www.kpaxpharmaceuticals.com
PH80-PMD	Pherin Pharmaceuticals <i>Los Altos, CA</i>	premenstrual dysphoric disorder, premenstrual syndrome	Phase II www.pherin.com
SRX246 (vasopressin 1a receptor antagonist)	Azevan Pharmaceuticals <i>Bethlehem, PA</i>	intermittent explosive disorder	Phase I/II www.azevan.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 March 29, 2016**. 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).

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.

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.