

2017 Medicines in Development for Mental Illnesses

Anxiety Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AVN-101 (serotonin6 receptor antagonist)	AllaChem Hallandale, FL Avineuro Pharmaceuticals San Diego, CA	anxiety	Phase II www.allachem.com www.avineuro.com
AVP-786 (dextromethorphan analogue/ quinidine)	Avanir Pharmaceuticals Aliso Viejo, CA Concert Pharmaceuticals Lexington, MA	agitation in Alzheimer's disease (Fast Track) (see also schizophrenia, other)	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) (see also depression)	Phase II/III www.axsome.com
ELND005 (amyloid beta-protein inhibitor)	Transition Therapeutics Toronto, Canada	agitation/aggression in Alzheimer's disease (Fast Track)	Phase II www.transitiontherapeutics.com
eltoprazine (serotonin 1A/1B partial agonist)	Amarantus BioScience San Francisco, CA	aggression in Alzheimer's disease (see also ADHD)	Phase II www.amarantus.com
FKW00GA (serotonin 1A receptor agonist, serotonin 2A receptor antagonist)	Fabre-Kramer Pharmaceuticals Houston, TX	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 (FAAH inhibitor)	Janssen Research & Development Raritan, NJ	social anxiety disorder	Phase II www.janssen.com
NBTX-001 (NMDA receptor antagonist)	Nobilis Therapeutics Portland, OR	panic disorder	Phase I www.nobilistx.com
Nuplazid® pimavanserin	ACADIA Pharmaceuticals San Diego, CA	agitation in Alzheimer's disease (see also depression, schizophrenia)	Phase II www.acadia-pharm.com
PH94B NS (sensory receptor cell modulator)	Pherin Pharmaceuticals Los Altos, CA	social anxiety disorder	Phase III www.pherin.com
Rexulti® brexpiprazole (oral)	Otsuka Pharmaceutical Rockville, MD	agitation in Alzheimer's disease (see also schizophrenia)	Phase III www.otsuka.com
		post-traumatic stress disorder (PTSD)	Phase II www.otsuka.com
SRX246 (vasopressin-1a receptor antagonist)	Azevan Pharmaceuticals Bethlehem, PA	PTSD	Phase II www.azevan.com
		anxiety	Phase I www.azevan.com

Anxiety Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Tonmya cyclobenzaprine very low dose	Tonix Pharmaceuticals New York, NY	PTSD (Breakthrough Therapy)	Phase III www.tonixpharma.com
Travivo™ gepirone ER	Fabre-Kramer Pharmaceuticals Houston, TX	generalized anxiety disorder (see also depression)	Phase II www.fabrekramer.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AEVI-1 (mGluR neuromodulator)	Aevi Genomic Medicine Wayne, PA	mGluR-positive genetic subset of attention-deficit/hyperactivity disorder (ADHD) (pediatric)	Phase II www.aevigenomics.com
ATS (dexamphetamine transdermal)	Noven Pharmaceuticals Miami, FL	ADHD	Phase II www.noven.com
Brintellix® vortioxetine	Lundbeck Deerfield, IL Takeda Deerfield, IL	ADHD (adult)	Phase III www.lundbeck.com www.takeda.com
centanafadine (triple reuptake inhibitor)	Neurovance Cambridge, MA	ADHD (adult)	Phase II www.neurovance.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CTX-1301	Cingulate Therapeutics Kansas City, KS	ADHD	Phase I www.cingulatetherapeutics.com
dasotraline (triple reuptake inhibitor)	Sunovion Pharmaceuticals Marlborough, MA	ADHD (adult and pediatric) (see also eating disorders)	application submitted www.sunovion.com
eltoprazine (serotonin 1A/1B partial agonist)	Amarantus BioScience San Francisco, CA	ADHD (adult) (see also anxiety)	Phase III www.amarantus.com
HLD100 (amphetamine novel formulation)	Highland Therapeutics Toronto, Canada Ironshore Pharmaceuticals Toronto, Canada	ADHD (pediatric)	Phase II www.highlandtherapeutics.com
HLD200 (methylphenidate novel formulation)	Highland Therapeutics Toronto, Canada Ironshore Pharmaceuticals Toronto, Canada	ADHD (adult and pediatric)	application submitted www.highlandtherapeutics.com
KP415 (methylphenidate ER)	KemPharma Celebration, FL	ADHD	Phase I www.kempharma.com
KP484 (methylphenidate ER)	KemPharma Celebration, FL	ADHD	Phase I www.kempharma.com

Attention-Deficit/Hyperactivity Disorder

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NLS-1 (mazindol CR)	NLS Pharma Stans, Switzerland	ADHD (adults)	Phase II www.neurolifesciences.com
ORADUR®-Methylphenidate ER methylphenidate sustained release	DURECT Cupertino, CA Orient Pharma Taipei, Taiwan	ADHD	Phase III www.durect.com
RP5063 (partial agonist of dopamine and serotonin)	Reviva Pharmaceuticals Santa Clara, CA	ADHD (see also bipolar, depression, schizophrenia)	Phase I completed www.revivapharma.com
SKL13865	SK Biopharmaceuticals Fair Lawn, NJ	ADHD	Phase I www.skbp.com
SPN-810 (molindone)	Supernus Pharmaceuticals Rockville, MD	impulse aggression in ADHD (pediatric) (Fast Track)	Phase III www.supernus.com
SPN-812 (adrenergic uptake inhibitor)	Supernus Pharmaceuticals Rockville, MD	ADHD	Phase II www.supernus.com
Vyvanse® lisdexamfetamine	Shire Lexington, MA	ADHD (4-5 years of age)	Phase III www.shire.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 Rockville, MD	bipolar 1 disorder (maintenance treatment)	application submitted www.otsuka.com
Geodon® ziprasidone	Pfizer New York, NY	bipolar 1 disorder (pediatric)	Phase III www.pfizer.com
ITI-007 (serotonin receptor antagonist)	Intra-Cellular Therapies New York, NY	bipolar depression (see also depression, schizophrenia)	Phase III www.intracellulartherapies.com
Latuda® lurasidone	Sunovion Pharmaceuticals Marlborough, MA	bipolar depression (pediatric)	application submitted www.sunovion.com
NRX-101 (cycloserine/lurasidone)	NeuroRx Wilmington, DE	acute suicidal ideation/behavior in bipolar depression (Fast Track)	Phase II www.neurorxpharma.com
RP5063 (partial agonist of dopamine and serotonin)	Reviva Pharmaceuticals Santa Clara, CA	bipolar disorder (see also ADHD, depression, schizophrenia)	Phase I www.revivapharma.com
Vraylar™ cariprazine	Allergan Parsippany, NJ	bipolar 1 depression (see also depression, schizophrenia)	Phase III 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 Waltham, MA	major depressive disorder (Fast Track)	application submitted www.alkermes.com
anti-depressant medicine	Kamat Pharmatech North Brunswick, NJ	depression	in clinical trials www.kamatpharma.com
apimostinel (partial NMDA receptor agonist)	Allergan Parsippany, NJ	major depressive disorder	Phase II www.allergan.com
AV-101 (NMDA receptor antagonist)	VistaGen Therapeutics South San Francisco, CA	major depressive disorder (adjunctive treatment)	Phase II www.vistagen.com
AXS-05 (bupropion/dextromethorphan fixed-dose combination)	Axsome Therapeutics New York, NY	treatment-resistant depression (Fast Track) (see also anxiety)	Phase III www.axsome.com
BLI-1005 (NET inhibitor)	BioLite Taipei, Taiwan	major depressive disorder	Phase II www.biolite.com.tw
Botox [®] onabotulinumtoxinA	Allergan Parsippany, NJ	major depressive disorder	Phase II www.allergan.com
BTRX-246040 (nociception receptor antagonist)	BlackThorn Therapeutics San Francisco, CA	major depressive disorder	Phase II www.blackthorn.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CERC-301 (NR2B-selective NMDA receptor antagonist)	Cerecor Baltimore, MD	major depressive disorder (Fast Track) (adjunctive treatment)	Phase II www.cerecor.com
CERC-501 (KOR antagonist)	Janssen Research & Development Raritan, NJ	major depressive disorder (adjunctive treatment) (see also substance abuse)	Phase II completed www.janssen.com
DB104 (liafensine)	Denovo Biopharma San Diego, CA	treatment-resistant depression	Phase II www.denovobiopharma.com
DSP-1200 (alpha2a adrenergic, dopamineD2, serotonin2A antagonist)	Sunovion Pharmaceuticals Marlborough, MA	treatment-resistant depression	Phase I www.sunovion.com
esketamine (intranasal) (NMDA receptor antagonist)	Janssen Research & Development Raritan, NJ	treatment-resistant depression (Fast Track), major depressive disorder (adjunctive treatment)	Phase III www.janssen.com
EVT100 (NR2B NMDA receptor antagonist)	Evotec Hamburg, Germany Janssen Research & Development Raritan, NJ	major depressive disorder	Phase I www.evotec.com www.janssen.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
FKB01MD (serotonin receptor agonist, serotonin receptor modulator, serotonin uptake inhibitor)	Fabre-Kramer Pharmaceuticals Houston, TX	major depressive disorder	Phase II www.fabrekramer.com
ganaxolone (GABA-A receptor agonist)	Marinus Pharmaceuticals Radnor, PA	postpartum depression	Phase II www.marinuspharma.com
ITI-007 (serotonin receptor antagonist)	Intra-Cellular Therapies New York, NY	major depressive disorder (see also bipolar, schizophrenia)	Phase II www.intracellulartherapies.com
JNJ-39393406 (alpha7 nicotinic acetylcholine receptor modulator)	Janssen Research & Development Raritan, NJ	depressive disorders	Phase II www.janssen.com
JNJ-54175446 (purinergic P2X7 receptor antagonist)	Janssen Research & Development Raritan, NJ	major depressive disorder	Phase I www.janssen.com
JNJ-55308942	Janssen Research & Development Raritan, NJ	mood disorders	Phase I www.janssen.com
LY03005 (dual uptake inhibitor)	Luye Pharma Group Shanghai, China	moderate to severe depression	Phase I www.luye.cn

Depression

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MIN-117 (serotonin receptor antagonist/ serotonin and dopamine reuptake inhibitor)	Minerva Neurosciences Waltham, MA	major depressive disorder	Phase II www.minervaneurosciences.com
MIN-202 (orexin2 antagonist)	Minerva Neurosciences Waltham, MA	major depressive disorder	Phase II completed www.minervaneurosciences.com
NSI-189 (neurogenesis stimulant)	Neuralstem Germantown, MD	major depressive disorder	Phase II www.neuralstem.com
Nuplazid® pimavanserin	ACADIA Pharmaceuticals San Diego, CA	major depressive disorder (adjunctive treatment) (see also anxiety, schizophrenia)	Phase II www.acadia-pharm.com
PH10 nasal spray (chemoreceptor cell modulator)	Pherin Pharmaceuticals Los Altos, CA	major depressive disorder	Phase II www.pherin.com
Pristiq® desvenlafaxine	Pfizer New York, NY	major depressive disorder (children and adolescents)	Phase III completed www.pfizer.com
rapastinel (NMDA receptor agonist)	Allergan Parsippany, NJ	major depressive disorder (Fast Track)	Phase III www.allergan.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
RP5063 (partial agonist of dopamine and serotonin)	Reviva Pharmaceuticals Santa Clara, CA	major depressive disorder (see also ADHD, bipolar, schizophrenia)	Phase I www.revivapharma.com
SAGE-217 (GABA A receptor modulator)	Sage Therapeutics Cambridge, MA	major depressive disorder, postpartum depression	Phase II www.sagerx.com
SAGE-547 (GABA A receptor modulator)	Sage Therapeutics Cambridge, MA	postpartum depression	Phase III www.sagerx.com
SPN-809	Supernus Pharmaceuticals Rockville, MD	depression	Phase I www.supernus.com
sirukumab (interleukin-6 inhibitor)	Janssen Research & Development Raritan, NJ	major depressive disorder	Phase II www.janssen.com
Strada™ ademetonine new oral formulation	MSI Methylation Sciences Burnaby, Canada	major depressive disorder (adjunctive treatment)	Phase II www.methylationsciences.com
SUVN-911 (alpha4, beta2 nicotinic receptor antagonist)	Suven Life Sciences Monmouth Junction, NJ	major depressive disorder	Phase I www.suven.com
Travivo™ gepirone ER	Fabre-Kramer Pharmaceuticals Houston, TX	major depressive disorder (see also anxiety)	application submitted www.fabrekramer.com

Depression

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
TS-121	Taisho Pharmaceutical R&D Morristown, NJ	major depressive disorder	Phase II www.taisho.co.jp
Viibryd® vilazodone	Allergan Parsippany, NJ	major depressive disorder (pediatric)	Phase III www.allergan.com
Vraylar™ cariprazine	Allergan Parsippany, NJ	major depressive disorder (adjunctive treatment) (see also bipolar, schizophrenia)	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 Marlborough, MA	binge eating disorder (see also ADHD)	Phase III www.sunovion.com
OPNT001 (opioid antagonist)	Opiant Pharmaceuticals Santa Monica, CA	binge eating disorder	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 Waltham, MA	schizophrenia	Phase III www.alkermes.com
ASP4345	Astellas Pharma US Northbrook, IL	cognitive impairment associated with schizophrenia (CIAS)	Phase I www.astellas.com
ASP6981	Astellas Pharma US Northbrook, IL	CIAS	Phase I www.astellas.com
ATI-9242 (serotonin7 receptor modulator)	Braeburn Pharmaceuticals Princeton, NJ	schizophrenia	Phase I www.braeburnpharmaceuticals.com
AVL-3288 (alpha7 nicotinic acetylcholine receptor modulator)	Anvyl Irvine, CA	CIAS	Phase I www.anvylinc.com
AVN-211 (serotonin 6 receptor antagonist)	AllaChem Hallandale Beach, FL Avineuro Pharmaceuticals San Diego, CA	schizophrenia	Phase II/III www.allachem.com www.avineuro.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AVP-786 (deuterated dextromethorphan/ quinidine)	Avanir Pharmaceuticals Aliso Viejo, CA Concert Pharmaceuticals Lexington, MA	residual schizophrenia symptoms (see also anxiety, other)	Phase II www.avinar.com www.concertpharma.com
basmisanil (GABA-A alpha5 receptor modulator)	Genentech South San Francisco, CA	CIAS	Phase II www.gene.com
BI-409306 (PDE9A inhibitor)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	schizophrenia	Phase II www.boehringer-ingelheim.com
DB103 (pomaglumetad)	Denovo Biopharma San Diego, CA	schizophrenia	Phase I www.denovopharma.com
DSP-6745	Sunovion Pharmaceuticals Marlborough, MA	Parkinson's disease psychosis	Phase I www.sunovion.com
FKF02SC (5HT2/D2 atypical antipsychotic)	Fabre-Kramer Pharmaceuticals Houston, TX	schizophrenia	Phase II www.fabrekramer.com
HP3070 (asenapine transdermal)	Noven Pharmaceuticals Miami, FL	schizophrenia	Phase III www.noven.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ITI-007 (serotonin receptor antagonist)	Intra-Cellular Therapies New York, NY	schizophrenia (see also bipolar, depression)	Phase III www.intracellulartherapies.com
ITI-214 (PDE1 inhibitor)	Intra-Cellular Therapies New York, NY	CIAS	Phase I www.intracellulartherapies.com
KarXT (trospium chloride/xanomeline)	Karuna Pharmaceuticals Boston, MA	schizophrenia	Phase I www.karunapharma.com
Lu AF35700 (dopamine D2 receptor modulator)	Lundbeck Deerfield, IL	treatment-resistant schizophrenia (Fast Track)	Phase III www.lundbeck.com
LY03004 (risperidone controlled release microspheres)	Luye Pharma Group Shanghai, China	schizophrenia	Phase III www.luye.cn
MIN-101 (serotonin 2A receptor antagonist/ sigma-2 receptor antagonist)	Minerva Neurosciences Waltham, MA	schizophrenia	Phase II www.minervaneurosciences.com
MK-8189	Merck Kenilworth, NJ	schizophrenia	Phase II www.merck.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NaBen® sodium benzoate ORPHAN DRUG	SyneuRx Taipei, Taiwan	schizophrenia (adjuvant therapy)	Phase II/III www.syneurx.com
Nuplazid® pimavanserin	ACADIA Pharmaceuticals San Diego, CA	schizophrenia (inadequate response) (see also anxiety, depression)	Phase III www.acadia-pharm.com
		Alzheimer's disease psychosis, schizophrenia (negative symptoms)	Phase II www.acadia-pharm.com
NW-3509 (evenamide) (potent sodium channel blocker)	Newron Pharmaceuticals Morristown, NJ	schizophrenia	Phase II www.newron.com
PF-04958242 (AMPA receptor modulator)	Pfizer New York, NY	schizophrenia	Phase I www.pfizer.com
RBP-7000 (risperidone 1 month depot in Atrigel®)	Indivior Richmond, VA	schizophrenia	application submitted www.indivior.com
Rexulti® brexpiprazole (depot injection)	Otsuka Pharmaceutical Rockville, MD	schizophrenia (pediatric) (see also anxiety)	Phase III www.otsuka.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
RG7203 (PDE10A inhibitor)	Genentech South San Francisco, CA	schizophrenia	Phase I www.gene.com
risperidone controlled-release implant	Braeburn Pharmaceuticals Princeton, NJ	schizophrenia	Phase III www.braeburnpharmaceuticals.com
Risperidone ISM[®] risperidone extended release	Laboratorios Farmacéuticos Rovi Madrid, Spain	acute schizophrenia	Phase III www.rovi.es
RP5063 (partial agonist of dopamine and serotonin)	Reviva Pharmaceuticals Santa Clara, CA	schizophrenia (see also ADHD, bipolar, depression)	Phase II completed www.revivapharma.com
		Alzheimer's disease psychosis, Parkinson's disease psychosis	Phase I completed www.revivapharma.com
SEP-363856	Sunovion Pharmaceuticals Marlborough, MA	Parkinson's psychosis, schizophrenia	Phase II www.sunovion.com
SKL20540	SK Biopharmaceuticals Fair Lawn, NJ	CIAS	Phase I www.skbp.com
TAK-041 (GPR139 agonist)	Takeda Deerfield, IL	CAIS (negative symptoms)	Phase I www.takeda.com

Schizophrenia

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
TAK-058 (serotonin 3 receptor antagonist)	Takeda Deerfield, IL	CAIS	Phase I www.takeda.com
TAK-831 (DAO inhibitor)	Takeda Deerfield, IL	schizophrenia	Phase I www.takeda.com
TS-134	Taisho Pharmaceutical R&D Morristown, NJ	schizophrenia	Phase I www.taisho.co.jp
Vraylar® cariprazine	Allergan Parsippany, NJ	schizophrenia (adults) (maintenance treatment) (see also anxiety, depression)	application submitted www.allergan.com
		schizophrenia (prevention of relapse)	Phase III completed www.allkergan.com

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 San Carlos, CA	drug use disorder	Phase I www.savanthwp.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AD04 (serotonin-3 receptor antagonist)	ADial Pharmaceuticals Charlottesville, VA	alcohol use disorder	Phase II www.adialpharma.com
		opioid use disorder, tobacco use disorder	Phase I completed www.adialpharma.com
ALKS 6428	Alkermes Waltham, MA	transition from opioid dependence to Vivitrol®	Phase III www.alkermes.com
amitifadine (adrenergic, dopamine, serotonin uptake inhibitor)	Euthymics Bioscience Cambridge, MA	alcohol use disorder	Phase II www.euthymics.com
ANS-6637 (ALDH2 inhibitor)	Amygdala Neurosciences Palo Alto, CA	substance use disorder	Phase I www.amygns.com
arbaclofen placarbil (GABA A receptor agonist)	Indivior Richmond, VA	alcohol use disorder	Phase II www.indivior.com
ARD-1600 (nicotine inhalation)	Aradigm Hayward, CA	tobacco use disorder	Phase I www.aradigm.com
buprenorphine/naloxone sublingual spray	INSYS Therapeutics Chandler, AZ	opioid use disorder	Phase II www.insysrx.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CAM-2038 (buprenorphine long-acting depot)	Braeburn Pharmaceuticals Princeton, NJ Camurus Lund, Sweden	opioid use disorder (Fast Track)	application submitted www.braeburnpharmaceuticals.com
cannabidiol (synthetic)	INSYS Therapeutics Chandler, AZ University of Chicago Chicago, IL	drug use disorder	Phase III completed www.insysrx.com
CERC-501 (selective KOR antagonist)	Janssen Research & Development Raritan, NJ	alcohol use disorder, tobacco use disorder (see also depression)	Phase II completed www.janssen.com
CORT-125134 (GR receptor antagonist)	Corcept Therapeutics Menlo Park, CA	alcohol use disorder	in clinical trials www.corcept.com
CVT-301 (inhaled L-Dopa)	Acorda Therapeutics Ardsley, NY	tobacco use disorder	Phase I completed www.acorda.com
cytisine (nicotinic receptor antagonist)	Achieve Life Sciences Bothell, WA	tobacco use disorder	Phase III www.achievelifesciences.com
EMB-001 (metyrapone/oxazepam)	Embera NeuroTherapeutics Sudbury, MA	cocaine use disorder, tobacco use disorder	Phase I www.emberaneuro.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
gabapentin enacarbil	Arbor Pharmaceuticals Atlanta, GA National Institute on Alcohol Abuse and Alcoholism Bethesda, MD	alcohol use disorder	Phase II completes www.arborpharma.com
GET 73 (gamma hydroxybutyric acid analogue)	CT Laboratories (Laboratorio Farmaceutico CT) Sanremo, Italy	alcohol use disorder	Phase I/II www.labct.it/en/
GSK561679 (CRF 1 receptor antagonist)	GlaxoSmithKline Research Triangle Park, NC National Institute on Alcohol Abuse and Alcoholism Bethesda, MD	alcohol use disorder	Phase II completed www.gsk.com
GW-42003 (cannabidiol)	GW Pharmaceutical Cambridge, United Kingdom Ichan School of Medicine New York, NY	opioid use disorder	Phase II www.gwpharm.com
INV-102 (nadolol)	Invion Brisbane, Australia	tobacco use disorder in COPD patients	Phase II completed www.inviogroup.com

Substance Use Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
JNJ-39393406 (alpha7 nicotinic acetylcholine receptor modulator)	Janssen Research & Development Raritan, NJ National Institutes of Health Bethesda, MD	tobacco use disorder (see also depression)	Phase II www.janssen.com
KW-6002 (istradefylline)	Kyowa Hakko Kirin Princeton, MA	drug use disorder	Phase I completed www.kyowa-kirin.com
lofexidine (alpha 2 adrenergic receptor agonist)	US WorldMeds Louisville, KY	opioid use disorder (Fast Track)	Phase III www.usworldmeds.com
MN-166 (ibudilast)	MediciNova La Jolla, CA National Institute on Drug Abuse Rockville, MD	alcohol use disorder, methamphetamine use disorder, opioid use disorder	Phase II www.medicinova.com
naloxone buccal gel (MDL-001)	Mucodel Greensboro, NC	opioid use disorder	Phase I www.exonal.com
naloxone intranasal	Amphastar Pharmaceuticals Rancho Cucamonga, CA	opioid use disorder	application submitted www.amphastar.com
naloxone intranasal	Indivior Richmond, VA	opioid use disorder (Fast Track)	application submitted www.indivior.com

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<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
naloxone sublingual spray	INSYS Therapeutics Chandler, AZ	reversal of opioid respiratory depression (Fast Track)	Phase III www.insysrx.com
nicotine transmucosal	Bionex Pharmaceuticals North Brunswick, NJ	tobacco use disorder	in clinical trials www.bionexpharma.com
noribogaine	DemeRx Fort Lauderdale, FL	opioid use disorder	Phase II
NS2359 (triple monoamine reuptake inhibitor)	Saniona Ballerup, Denmark University of Pennsylvania Pittsburgh, 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
OPNT002 (opioid antagonist nasal spray)	Opiant Pharmaceuticals Santa Monica, CA National Institute on Drug Abuse Rockville, MD	alcohol use disorder	Phase II www.opiant.com
RBP-6000 (buprenorphine one-month depot in Atrigel®)	Indivior Richmond, VA	opioid use disorder (Fast Track)	application submitted www.indivior.com

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<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
RBP-8000 (cocaine esterase)	Indivior Richmond, VA	cocaine use disorder	Phase II completed www.indivior.com
REL-1028 (oral buprenorphine)	Relmada Therapeutics New York, NY	opioid use disorder	Phase I www.relmada.com
SELA-070 (immune-stimulation 2nd-generation vaccine)	Selecta Biosciences Watertown, MA	tobacco use disorder and relapse prevention	Phase I www.selectabio.com
TA-CD vaccine	Celtic Pharma Bermuda National Institute on Drug Abuse Rockville, MD	cocaine use disorder	Phase II
Vivitrol® naltrexone controlled release in combination with buprenorphine	Alkermes Waltham, MA	opioid use disorder (combination therapy)	Phase III completed www.alkemes.com
X-22 (very low-dose nicotine)	22nd Century Westport, CT	tobacco use disorder	Phase II www.xxiicentury.com

Other Disorders

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ANAVEX™ 2-73	Anavex Life Sciences New York, NY	cognition in neuropsychiatric disorders	Phase I www.anavex.com
AR19	Arbor Pharmaceuticals Atlanta, GA	mental illnesses (pediatric)	Phase III www.arborpharma.com
AR20	Arbor Pharmaceuticals Atlanta, GA	mental illnesses (pediatric)	Phase III www.arborpharma.com
AR30	Arbor Pharmaceuticals Atlanta, GA	mental illnesses	Phase II www.arborpharma.com
AVP-786 (deuterated dextromethorphan/ quinidine)	Avanir Pharmaceuticals Aliso Viejo, CA Concert Pharmaceuticals Lexington, MA	disinhibition syndrome in neuro- degenerative disorders (see also anxiety, schizophrenia)	Phase II www.avinar.com www.concertpharma.com
RG7906	Genentech South San Francisco, CA	psychiatric disorders	Phase I www.gene.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 September 20, 2017**. 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.