



Estimated dates are subject to change due to patent litigation, additional patents, exclusivities...

Estimated Dates of Possible First Time Generic/ Rx-to-OTC Market Entry

Year	Period	Brand Name	Generic name	Common use(s)	2010 US Retail Sales: (in millions)^
2012	1Q (Jan)	<i>Symbyax</i> [®]	olanzapine/fluoxetine	Treatment-resistant depression, depression in Bipolar I Disorder	\$89
2012	1Q (Mar)	<i>Geodon</i> [®]	ziprasidone	Schizophrenia, bipolar disorder	\$1,059
2012	1Q (Mar)	<i>Lexapro</i> ^{®1}	escitalopram	Depression, anxiety	\$2,591
2012	1Q (Mar)	<i>Seroquel</i> [®]	quetiapine	Schizophrenia, bipolar disorder	\$3,549
2012	1Q (Mar)	<i>Avandia</i> [®]	rosiglitazone	Type 2 diabetes	\$286
2012	1Q (Mar)	<i>Avandamet</i> [®]	rosiglitazone/ metformin	Type 2 diabetes	\$161
2012	1Q (Mar)	<i>Avandaryl</i> [®]	glimepiride/ rosiglitazone	Type 2 diabetes	\$35
2012	1Q (Mar)	<i>Avapro</i> [®]	irbesartan	High blood pressure	\$398
2012	1Q (Mar)	<i>Avalide</i> [®]	irbesartan/ hydrochlorothiazide	High blood pressure	\$341
2012	2Q (Apr)	<i>Provigil</i> [®]	modafinil	Excessive sleepiness	\$1,014
2012	2Q (May)	<i>Plavix</i> ^{®3}	clopidogrel (approved 1/06 and briefly launched 8/06)	Prevent blood clots	\$5,020
2012	2Q (May)	<i>Viramune</i> [®]	nevirapine	HIV infection	\$108
2012	2Q (Jun)	<i>Lescol</i> [®] and <i>Lescol</i> [®] XL	fluvastatin	High cholesterol	Lescol: \$26 Lescol XL: \$67
2012	3Q (Jul)	<i>Tricor</i> [®]	fenofibrate	High cholesterol	\$1,123
2012	3Q (Jul)	<i>Clarinet</i> [®] & <i>Clarinet-D</i> [®] (planning OTC prior to generic availability) ²	desloratadine and desloratadine/ pseudoephedrine	Allergy symptoms, hives	Clarinet: \$177 Clarinet D: \$32
2012	3Q (Aug)	<i>Singulair</i> [®]	montelukast	Asthma, allergy symptoms	\$3,824
2012	3Q (Aug)	<i>Actos</i> [®]	pioglitazone	Type 2 diabetes	\$2,914
2012	3Q (Aug)	<i>Xopenex</i> [®] (not HFA) ⁴	levalbuterol inhalation solution	Asthma, COPD	\$415
2012	3Q (Sep)	<i>Revatio</i> [®]	sildenafil	Pulmonary arterial hypertension	\$178

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2012	3Q (Sep)	<i>Diovan[®] and Diovan[®] HCT⁵</i>	valsartan and valsartan/ hydrochlorothiazide	High blood pressure	Diovan: \$1,585 Diovan HCT: \$1,431
2012	3Q (Sep)	<i>Detrol[®]</i>	tolterodine	Overactive bladder	\$46
2012	4Q (Nov)	<i>Lidoderm[®]</i>	lidocaine topical patch	Pain due to post-herpetic neuralgia	\$1,066
2012	4Q (Dec)	<i>Atacand[®] and Atacand HCT[®]</i>	candesartan and candesartan/ hydrochlorothiazide	High blood pressure	Atacand: \$122 Atacand HCT: \$59
2012	4Q (Dec)	<i>Evoxac[®]</i>	cevimeline	Sjögren's syndrome	\$41
2012	4Q (Dec)	<i>Maxalt[®] and Maxalt-MLT[®]</i>	rizatriptan	Migraines	Maxalt: \$278 Maxalt-MLT: \$232
2012	4Q (Dec)	<i>Actoplus Met[®]</i>	pioglitazone/ metformin	Type 2 diabetes	\$431
2013	1Q (Jan)	<i>Opana[®] ER</i>	oxymorphone extended-release tablet (previously approved, not launched 6/10)	Pain	\$405
2013	1Q (Mar)	<i>Zometa[®]</i>	zoledronic acid injection	Hypercalcemia of malignancy, reduce bone complications from cancer	\$5
2013	1Q (Mar)	<i>Valcyte[®]</i>	valganciclovir	Viral infections	\$195
2013	2Q (May)	<i>Zomig[®]</i>	zolmitriptan	Migraines	\$141
2013	2Q (Jun)	<i>Fosamax Plus DTM</i>	alendronate / cholecalciferol	Osteoporosis	\$59
2013	2Q (Jun)	<i>Rilutek[®]</i>	riluzole (generic approved, not launched 1/03)	Amyotrophic lateral sclerosis	\$36
2013	3Q (Aug)	<i>Temodar^{®66}</i>	temozolomide (generic approved, not launched 3/10)	Glioblastoma multiforme	\$189
2013	3Q (Aug)	<i>Cerezyme[®]</i>	imiglucerase injection	Gaucher Disease	\$1
2013	3Q (Sep)	<i>Niaspan[®]</i>	niacin extended-release tablet	High cholesterol	\$889
2013	3Q (Sep)	<i>Advicor[®]</i>	lovastatin/niacin	High cholesterol	\$55
2013	4Q (Nov)	<i>AcipHex[®]</i>	rabeprazole (tablets approved but not launched 2/07)	GERD	\$1,007

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2013	4Q (Dec)	<i>Vivelle-DOT</i> [®]	estradiol extended-release film	Menopausal symptoms	\$198
2013	4Q (Dec)	<i>Cymbalta</i> [®]	duloxetine	Depression, anxiety, nerve/musculoskeletal pain, fibromyalgia	\$2,891
2014	1Q (Jan)	<i>Rapamune</i> [®]	sirolimus	Prevent organ rejection	\$139
2014	1Q (Jan)	<i>Micardis</i> [®] and <i>Micardis</i> [®] HCT	telmisartan and telmisartan/hydrochlorothiazide	High blood pressure	Micardis: \$253 Micardis HCT: \$218
2014	1Q (Jan)	<i>Loestrin</i> [®] 24 Fe ⁷	ethinyl estradiol/norethindrone	Contraception	\$633
2014	1Q (Jan)	<i>Asacol</i> [®]	mesalamine delayed-release tablet	Ulcerative colitis	\$577
2014	1Q (Jan)	<i>Trilipix</i> [®]	fenofibric acid	High cholesterol	\$490
2014	1Q (Feb)	<i>Avelox</i> [®]	moxifloxacin	Bacterial infections	\$406
2014	1Q (Feb)	<i>Enbrel</i> [®]	etanercept injection	Rheumatoid arthritis, JIA, plaque psoriasis, ankylosing spondylitis	\$1,360
2014	1Q (Mar)	<i>Evista</i> [®]	raloxifene	Osteoporosis, reduce risk of breast cancer	\$522
2014	2Q (Apr)	<i>Viracept</i> [®]	nelfinavir	HIV infection	\$51
2014	2Q (May)	<i>Nexium</i> [®]	esomeprazole	GERD, ulcers	\$5,586
2014	2Q (May)	<i>Celebrex</i> [®]	celecoxib	Pain	\$1,497
2014	2Q (May)	<i>Lunesta</i> [®]	eszopiclone	Insomnia	\$818
2014	2Q (May)	<i>Lupron</i> [®] 3.75 mg	leuprolide injection	Endometriosis, fibroids	NA
2014	2Q (Jun)	<i>Actonel</i> [®] with calcium	risedronate/calcium	Osteoporosis	\$1
2014	2Q (Jun)	<i>Actonel</i> [®]	risedronate	Osteoporosis	\$663
2014	2Q (Jun)	<i>Xeloda</i> [®]	capecitabine	Colorectal, breast cancers	\$290
2014	2Q (Jun)	<i>Tazorac</i> [®] gel	Tazarotene gel	Acne	\$123 (cream and gel)
2014	3Q (Jul)	<i>Nasonex</i> [®]	mometasone nasal spray	Allergic rhinitis	\$1,108

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2014	3Q (Aug)	<i>Lumigan</i> [®]	bimatoprost ophthalmic solution	Glaucoma, ocular hypertension	\$303
2014	3Q (Sep)	<i>Renagef</i> [®]	sevelamer	Chronic kidney disease	\$171
2014	4Q (Oct)	<i>TOBI</i> [®]	tobramycin inhalation	<i>P. aeruginosa</i> infection in cystic fibrosis	\$155
2014	4Q (Nov)	<i>Copaxone</i> [®]	glatiramer injection	Multiple sclerosis	\$439
2015	1Q (Jan)	<i>Cipro</i> [®] HC	ciprofloxacin/hydrocortisone otic suspension	Bacterial external and middle ear infections	\$40
2015	1Q (Jan)	<i>Norvir</i> [®]	ritonavir	HIV infection	\$386
2015	1Q (Jan)	<i>Namenda</i> [®]	memantine (generic approved 4/14/10, not launched)	Alzheimer's disease	\$796
2015	1Q (Feb)	<i>Tarka</i> [®]	trandolapril/verapamil	High blood pressure	\$30
2015	1Q (Mar)	<i>Hepsera</i> [®]	adefovir dipivoxil	Chronic hepatitis B	\$73
2015	1Q (Mar)	<i>Sustiva</i> [®]	efavirenz	HIV infection	\$150
2015	1Q (Mar)	<i>Renvela</i> [®]	sevelamer	Chronic kidney disease	\$295
2015	1Q (Mar)	<i>Lovaza</i> [®]	omega-3-acid ethyl esters	High triglycerides	\$806
2015	2Q (Apr)	<i>Namenda</i> [®]	memantine oral solution	Alzheimer's disease	\$796 (all formulations)
2015	2Q (Apr)	<i>Oxytrol</i> [®]	oxybutynin extended-release film	Overactive bladder	\$23
2015	2Q (Apr)	<i>Abilify</i> [®]	aripiprazole	Schizophrenia, bipolar disorder, autistic disorder, depression	\$4,077
2015	2Q (May)	<i>Zyvox</i> [®]	linezolid	Bacterial infections	\$253
2015	2Q (May)	<i>Avodart</i> [®]	dutasteride	Benign prostatic hyperplasia	\$486
2015	2Q (May)	<i>Epogen</i> [®]	epoetin alfa injection	Anemia	\$15
2015	2Q (May)	<i>Procrit</i> [®]	epoetin alfa injection	Anemia	\$208
2015	2Q (Jun)	<i>WelChol</i> [®]	colesevelam	High cholesterol	\$332

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2015	2Q (Jun)	<i>Travatan[®] and Travatan Z[®]</i>	travoprost ophthalmic solution	Glaucoma, ocular hypertension	Travatan: \$73 Travatan Z: \$298
2015	3Q (Jul)	<i>Aggrenox[®]</i>	aspirin/dipyridamole extended-release capsule	Prevent blood clots	\$288
2015	3Q (Jul)	<i>Gleevec[®]</i>	imatinib	Chronic myeloid leukemia, gastrointestinal stromal tumors	\$603
2015	3Q (Jul)	<i>Pulmozyme[®]</i>	dornase alfa inhalation solution	Cystic fibrosis	\$176
2015	3Q (Aug)	<i>AndroGel[®]</i>	testosterone gel	Low testosterone	\$761
2015	3Q (Sep)	<i>Intuniv[®]</i>	guanfacine extended-release tablets	ADHD	\$175
2015	4Q (Oct)	<i>Aloxi[®]</i>	palonosetron	Nausea, vomiting	\$1
2015	4Q (Oct)	<i>Neulasta[®]</i>	pegfilgrastim injection	Neutropenia	\$94
2015	4Q (Oct)	<i>Synagis[®]</i>	palivizumab injection	Respiratory syncytial virus	\$4
2015	4Q (Dec)	<i>Pataday[™]</i>	olopatadine ophthalmic solution	Allergic conjunctivitis	\$233
2015	4Q (Dec)	<i>Patanol[®]</i>	olopatadine ophthalmic solution	Allergic conjunctivitis	\$251
2015	4Q (Dec)	<i>Combivent[®]</i>	albuterol/ipratropium inhalation	COPD	\$738
2015	4Q (Dec)	<i>Fuzeon[®]</i>	enfuvirtide injection	HIV infection	\$17
2015	4Q (Dec)	<i>Coreg CR[®]</i>	carvedilol extended-release capsules	High blood pressure	\$261
2015	4Q (Dec)	<i>Ortho Tri-Cyclen Lo[®]</i>	ethinyl estradiol/norgestimate	Contraception	\$400
2015	4Q (Dec)	<i>Teveten[®]</i>	eprosartan 400 mg tablet	High blood pressure	Teveten (all strengths): \$5
2016	1Q (Mar)	<i>Epzicom[®] tablets</i>	abacavir/lamivudine tablets	HIV infection	\$349
2016	2Q (May)	<i>Ortho Evra[®]</i>	ethinyl estradiol/norelgestromin transdermal system	Contraception	\$138
2016	2Q (Jun)	<i>Focalin XR[®]</i>	dexmethylphenidate extended-release capsule	ADHD	\$496

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2016	2Q (Jun)	<i>Enablex</i> [®]	darifenacin extended-release tablets	Overactive bladder	\$223
2016	3Q (Jul)	<i>Crestor</i> [®]	rosuvastatin calcium	High cholesterol	\$3,277
2016	3Q (Sep)	<i>Rituxan</i> [®]	rituximab injection	Rheumatoid arthritis, NHL, CLL	\$10
2016	4Q (Oct)	<i>Benicar</i> [®] & <i>Benicar</i> [®] HCT	olmesartan & olmesartan/hydrochlorothiazide	High blood pressure	Benicar: \$620 Benicar HCT: \$569
2016	4Q (Oct)	<i>Spectracef</i> [®]	cefditoren pivoxil	Bacterial infections	\$9
2016	4Q (Oct)	<i>Azor</i> [®]	amlodipine 10mg/olmesartan 20mg	High blood pressure	\$195 (all strengths)
2016	4Q (Nov)	<i>Seroquel XR</i> [®]	quetiapine extended-release tablets	Schizophrenia, depression, bipolar disorder	\$765
2016	4Q (Dec)	<i>Lupron</i> [®]	leuprolide injection	Advanced prostate cancer	\$112
2016	4Q (Dec)	<i>Kaletra</i> [®]	lopinavir/ritonavir tablet	HIV infection	\$321
2016	4Q (Dec)	<i>Zetia</i> [®]	ezetimibe	High cholesterol	\$1,060
2016	4Q (Dec)	<i>Humira</i> [®]	adalimumab injection	Rheumatoid arthritis, JIA, ankylosing spondylitis, Crohn's disease, plaque psoriasis	\$1,205
2016	4Q (Dec)	<i>Norvir</i> [®]	ritonavir 100 mg tablets	HIV infection	\$386 (all strengths)
2017	1Q (Jan)	<i>Sandostatin</i> [®]	octreotide injection	Acromegaly, carcinoid syndrome	\$33
2017	2Q (Apr)	<i>Vytorin</i> [®]	ezetimibe/simvastatin	High cholesterol	\$1,034
2017	2Q (May)	<i>Velcade</i> [®]	bortezomib injection	Multiple myeloma, lymphoma	\$4
2017	2Q (May)	<i>Strattera</i> [®]	atomoxetine	ADHD	\$533
2017	2Q (Jun)	<i>Relpax</i> [®]	eletriptan	Migraines	\$233
2017	2Q (Jun)	<i>Tamiflu</i> [®]	oseltamivir capsules	Influenza	\$124
2017	3Q (Sep)	<i>Cancidas</i> [®]	caspofungin injection	Fungal infections	\$0.2

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2017	4Q (Nov)	<i>Adcirca</i> [®]	tadalafil	Pulmonary arterial hypertension	\$8
2017	4Q (Dec)	<i>Exforge</i> [®]	amlodipine/valsartan	High blood pressure	\$286
2018	1Q (Jan)	<i>Follistim</i> [®]	follitropin beta vial	Infertility	\$63 (all forms)
2018	1Q (Jan)	<i>Viread</i> [®]	tenofovir 300 mg tablet	Chronic hepatitis B infection	\$335
2018	2Q (May)	<i>Cialis</i> [®]	tadalafil	Erectile dysfunction	\$754
2018	3Q (Jul)	<i>Letairis</i> [®]	ambrisentan	Pulmonary arterial hypertension	\$1
2018	3Q (Aug)	<i>Solodyn</i> [®] ER	minocycline extended-release tablets	Acne	\$898
2018	3Q (Sep)	<i>Remicade</i> [®]	infliximab injection	Rheumatoid arthritis, Crohn's disease, plaque psoriasis	\$24
2018	3Q (Sep)	<i>Nitrostat</i> [®]	nitroglycerin sublingual tablets	Angina	\$12
2018	3Q (Sep)	<i>Sensipar</i> [®]	cinacalcet	Hyperparathyroidism, hypercalcemia	\$385
2018	4Q (Oct)	<i>NuvaRing</i> [®]	ethinyl estradiol/etonogestrel vaginal ring	Contraception	\$439
2018	4Q (Nov)	<i>Tyvaso</i> [®]	treprostinil inhalation solution	Pulmonary arterial hypertension	\$0.5
2018	4Q (Nov)	<i>Tarceva</i> [®]	erlotinib	Non-small cell lung cancer	\$245
2018	4Q (Dec)	<i>Xolair</i> [®]	omalizumab injection	Allergic asthma	\$2
2019	1Q (Jan)	<i>Exelon</i> [®] Patch	rivastigmine extended-release film	Alzheimer's disease	\$303
2019	1Q (Jan)	<i>Tekturna</i> [®] and <i>Tekturna HCT</i> [®]	aliskiren and aliskiren/hydrochlorothiazide	High blood pressure	Tekturna: \$147 Tekturna HCT: \$38
2019	1Q (Feb)	<i>Gilenya</i> [™]	fingolimod	Multiple sclerosis	\$1
2019	1Q (Feb)	<i>Advate</i> [®]	antihemophilic factor, recombinant	Hemophilia A	\$1
2019	2Q (Apr)	<i>BeneFIX</i> [®]	coagulation factor IX, recombinant	Hemophilia B	\$0.9
2019	2Q (Apr)	<i>Exjade</i> [®]	deferasirox	Chronic iron overload	\$12
2019	2Q (May)	<i>Vesicare</i> [®]	solifenacin	Overactive bladder	\$471

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2019	2Q (Jun)	<i>Reyataz</i> [®]	atazanavir	HIV infection	\$665
2019	2Q (Jun)	<i>Lyrica</i> [®]	pregabalin	Fibromyalgia, nerve pain, seizures	\$1,571
2019	3Q (Aug)	<i>Follistim</i> [®]	follitropin beta cartridge	Infertility	\$63 (all forms)
2019	4Q (Oct)	<i>Orencia</i> [®]	abatacept injection	Rheumatoid arthritis	\$5
2019	4Q (Oct)	<i>Revlimid</i> [®]	lenalidomide	Multiple myeloma, myelodysplastic syndromes	\$112
2019	4Q (Nov)	<i>Pegasys</i> [®]	peginterferon alfa-2a injection	Chronic hepatitis B, Chronic hepatitis C	\$193
2019	4Q (Dec)	<i>Zytiga</i> [®]	abiraterone	Prostate cancer	NA
2020	1Q (Jan)	<i>Nexavar</i> [®]	sorafenib	Renal cell cancer, liver cancer	\$18
2020	1Q (Mar)	<i>Vigamox</i> [®]	moxifloxacin ophthalmic solution	Bacterial conjunctivitis	\$289
2020	2Q (Apr)	<i>Bystolic</i> [®]	nebivolol	High blood pressure	\$244
2020	2Q (Apr)	<i>Viagra</i> [®]	sildenafil	Erectile dysfunction	\$1,011
2020	2Q (May)	<i>Detrol</i> [®] LA	tolterodine	Overactive bladder	\$643
2020	2Q (Jun)	<i>Dexilant</i> [®]	dexlansoprazole delayed-release capsule	GERD, erosive esophagitis	\$252
2020	2Q (Jun)	<i>Lialda</i> [®]	mesalamine delayed-release tablet	Ulcerative colitis	\$290
2020	3Q (Jul)	<i>Byetta</i> [®]	exenatide injection	Type 2 diabetes	\$505
2020	3Q (Sep)	<i>Tykerb</i> [®]	lapatinib	Breast cancer	\$15
2020	4Q (Nov)	<i>Chantix</i> [®]	varenicline	Smoking cessation	\$425
2020	4Q (Nov)	<i>Kaletra</i> [®]	lopinavir/ritonavir oral solution	HIV infection	\$321
2021	2Q (May)	<i>Zomig</i> [®] spray	zolmitriptan nasal spray	Migraines	\$24
2021	3Q (Aug)	<i>Crixivan</i> [®]	indinavir	HIV infection	\$7

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2021	3Q (Aug)	<i>Sutent</i> [®]	sunitinib	Renal cell carcinoma, GIST, pancreatic neuroendocrine tumors	\$109
2021	3Q (Sep)	<i>Truvada</i> [®]	tenofovir/emtricitabine	HIV infection	\$1,268
2022	1Q (Jan)	<i>Alphagan</i> [®] P	brimonidine ophthalmic solution	Glaucoma, ocular hypertension	\$155
2022	2Q (Apr)	<i>Oracea</i> [®]	doxycycline	Rosacea	\$258
2022	3Q (Aug)	<i>Victoza</i> [®]	liraglutide injection	Type 2 diabetes	\$194
2023	1Q (Mar)	<i>Differin</i> [®]	adapalene 0.3% gel	Acne	NA
2023	2Q (May)	<i>Boniva</i> [®]	ibandronate	Osteoporosis	\$563
2023	2Q (Jun)	<i>Vyvanse</i> [®]	lisdexamfetamine	ADHD	\$1,078
2023	3Q (Sep)	<i>Proair</i> [®] HFA	albuterol inhalation	Asthma	\$964
2023	3Q (Sep)	<i>Stelara</i> [®]	ustekinumab injection	Plaque psoriasis	\$37
2023	4Q (Dec)	<i>Thalomid</i> [®]	thalidomide	Multiple myeloma, erythema nodosum leprosum	\$117
2024	1Q (Feb)	<i>Cimzia</i> [®]	certolizumab injection	Rheumatoid arthritis, Crohn's disease	\$51
2024	2Q (Jun)	<i>Xyrem</i> [®]	sodium oxybate 500 mg/mL oral solution	Narcolepsy	\$0.028
2025	4Q (Nov)	<i>Kuvan</i> [®]	sapropterin	Phenylketonuria	NA
2026	1Q (Jan)	<i>Ampyra</i> [®]	dalfampridine extended-release tablets	Multiple sclerosis	\$1
2026	1Q (Mar)	<i>Simponi</i> [®]	golimumab injection	Rheumatoid arthritis	\$98
2026	3Q (Sep)	<i>Avonex</i> [®] Administration Pack	interferon beta-1a injection	Multiple sclerosis	\$329
2026	3Q (Sep)	<i>Betaseron</i> [®]	interferon beta-1b injection	Multiple sclerosis	\$164
2026	3Q (Sep)	<i>Rebit</i> [®]	interferon beta-1a injection	Multiple sclerosis	\$152
2026	4Q (Oct)	<i>Janumet</i> [®]	metformin/sitagliptin	Type 2 diabetes	\$543

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2026	4Q (Oct)	Januvia®	sitagliptin	Type 2 diabetes	\$1,434
2027	1Q (Mar)	Spiriva®	tiotropium powder for inhalation	COPD	\$1,703

^ Dollar amount reflects combined sales of all strengths and formulations of the product, unless otherwise indicated; source IMS Health

¹ Lexapro's '712 patent was originally slated to expire in December 2009, which included an additional six months of pediatric exclusivity. The U.S. Patent & Trademark Office granted the patent an 828-day extension in March 2006. Therefore, the estimated date for generic availability changed to March 2012. A recent patent litigation decision has also sided with Forest, upholding the validity of a key patent on Lexapro and keeping generics off the market until patent expiration in 2012.

² Several companies have announced the settlement of patent litigation relating to Desloratadine Tablets, 5 mg (Clarinet). Pursuant to these settlements, the generic manufacturers will have the right to market Desloratadine Tablets, 5 mg, in the U.S. on July 1, 2012, or earlier in certain circumstances. Clarinet and Clarinet D will likely be switched to OTC availability prior to generic availability.

³ Generic Plavix was approved 1/20/06 with paragraph IV certification giving Apotex 180-day exclusivity. Apotex launched their generic "at risk" on August 8, 2006. A preliminary injunction was granted on August 31, ordering Apotex to halt its sales of generic Plavix. The judge did not require Apotex to recall clopidogrel that had already been distributed. Bristol-Myers Squibb/Sanofi's patent infringement trial against Apotex began January 22, 2007.

⁴ Mylan launched their first-time generic for Xopenex inhalation solution 0.25% with 180 day exclusivity in September 2009. In April 2008, Breath Limited received FDA approval for their generic Xopenex inhalation solution 0.021%, .0042%, and 0.0103%. Sepracor settled a patent dispute with them which will allow Breath to market generic versions of the drug beginning August 2012 with a 180-day exclusive license. In March 2009, Sepracor entered into a Settlement and License Agreement with Teva and Barr. The agreement permits Barr and Teva to launch generic versions of Xopenex inhalation solution dosages under terms of a non-exclusive license commencing on February 17, 2013.

⁵ Diovan received pediatric exclusivity, extending the drug's patent protection in the US until September 2012.

⁶ Patent litigation is ongoing between Teva and Merck with regard to Temodar. The U.S. Court of Appeals for the Federal Circuit court is reviewing an appeal by Merck. If the Appeals court agrees that Merck's patent for Temodar is unenforceable, Teva may launch their generic at any time.

⁷ Warner Chilcott sued Watson for patent infringement on Loestrin 24 FE in 2006. A settlement was reached in January 2009. Warner Chilcott sued Lupin for patent infringement on Loestrin 24 FE in September 2009.

⁸ In October 2007, Teva received FDA approval of its ANDA for Actonel 5 mg, 30 mg, and 35 mg tablets but did not launch due to ongoing patent litigation. In February 2008, the U.S. District Court for the District of Delaware found Procter & Gamble's U.S. Patent No. 5,538,122 covering Actonel to be valid. Teva intends to appeal this decision.

Information current as of January 2012. Estimated dates are subject to change due to patent litigation, additional patents, exclusivities...



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⁹ Boehringer Ingelheim sued Teva/Barr for patent infringement on Aggrenox in July 2007. The companies announced a settlement agreement in August 2008.

Note: Pulmicort dry powder inhalation and Advair have been removed from the table. These both contain inhaled corticosteroids, and the FDA has not determined a standard for bioequivalence for inhaled corticosteroids in multi-dose inhalers (MDIs) or dry powder inhalers (DPIs). Therefore, generic availability may be significantly delayed. At this time, there is no estimated date of generic approval.

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