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

Year	Period	Brand Name	Generic name	2009 US Retail Sales: (in millions)^
2011	1Q (Mar)	<i>Xalatan</i> [®]	latanoprost	\$520
2011	2Q (Apr)	<i>Aromasin</i> [®]	exemestane	\$129
2011	2Q (Apr)	<i>Femara</i> [®]	letrozole	\$462
2011	2Q (May)	<i>Concerta</i> [®]	methylphenidate extended-release tablet	\$1,327
2011	2Q (Jun)	<i>Nasacort AQ</i> [®]	triamcinolone nasal spray (previously approved, not launched 7/09)	\$272
2011	2Q (Jun)	<i>Levaquin</i> [®]	levofloxacin	\$1,633
2011	3Q (Jul)	<i>Uroxatral</i> [®]	alfuzosin extended- release tablet	\$196
2011	3Q (Jul)	<i>Anzemet</i> [®]	dolasetron	\$8
2011	4Q (Oct)	<i>Zyprexa</i> [®] and <i>Zyprexa</i> [®] <i>Zydis</i>	olanzapine	Zyprexa: \$1,968 Zydis: \$156
2011	4Q (Oct)	<i>Malarone</i> [®]	atovaquone/proguanil	\$60
2011	4Q (Nov)	<i>Solodyn</i> [®]	minocycline extended- release tablet (previously approved, briefly launched)	\$588
2011	4Q (Nov)	<i>Lipitor</i> [®]	atorvastatin	\$6,054
2011	4Q (Nov)	<i>Caduet</i> [®]	amlodipine/ atorvastatin	\$362
2011	4Q (Dec)	<i>Tazorac</i> [®]	tazarotene	\$111
2011	4Q (Dec)	<i>Combivir</i> [®]	lamivudine/zidovudine	\$280
2012	1Q (Jan)	<i>Clarinet</i> [®] & <i>Clarinet-D</i> [®] (planning OTC prior to generic availability) ¹	desloratadine and desloratadine/ pseudoephedrine	Clarinet: \$217 Clarinet D: \$39
2012	1Q (Mar)	<i>Lexapro</i> ^{®2}	escitalopram	\$2,557
2012	1Q (Mar)	<i>Seroquel</i> [®]	quetiapine	\$3,483

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2012	1Q (Mar)	<i>Gabitril</i> [®]	tiagabine	\$55
2012	1Q (Mar)	<i>Avandia</i> [®]	rosiglitazone	\$437
2012	1Q (Mar)	<i>Avandamet</i> [®]	rosiglitazone/ metformin	\$207
2012	1Q (Mar)	<i>Avandaryl</i> [®]	glimepiride/ rosiglitazone	\$48
2012	1Q (Mar)	<i>Avapro</i> [®]	irbesartan	\$414
2012	1Q (Mar)	<i>Avalide</i> [®]	irbesartan/ hydrochlorothiazide	\$359
2012	2Q (Apr)	<i>Provigil</i> [®]	modafinil	\$967
2012	2Q (May)	<i>Plavix</i> [®]	clopidogrel (approved 1/06 and briefly launched 8/06)	\$4,563
2012	2Q (May)	<i>Viramune</i> [®]	nevirapine	\$109
2012	2Q (Jun)	<i>Lescol</i> [®] and <i>Lescol</i> [®] XL	fluvastatin	Lescol: \$32 Lescol XL: \$88
2012	3Q (Jul)	<i>Femcon</i> [®] Fe	ethinyl estradiol/ norethindrone	\$61
2012	3Q (Jul)	<i>Tricor</i> [®]	fenofibrate	\$1,350
2012	3Q (Aug)	<i>Singulair</i> [®]	montelukast	\$3,466
2012	3Q (Aug)	<i>Actos</i> [®]	pioglitazone	\$2,783
2012	3Q (Aug)	<i>Xopenex</i> [®] (not HFA) ⁴	levalbuterol inhalation solution	\$477
2012	3Q (Sep)	<i>Revatio</i> [®]	sildenafil	\$182
2012	3Q (Sep)	<i>Diovan</i> [®] and <i>Diovan</i> [®] HCT ⁵	valsartan and valsartan/ hydrochlorothiazide	Diovan: \$1,470 Diovan HCT: \$1,376
2012	3Q (Sep)	<i>Geodon</i> [®]	ziprasidone	\$976
2012	3Q (Sep)	<i>Detrol</i> [®]	tolterodine	\$46
2012	4Q (Nov)	<i>Lidoderm</i> [®]	lidocaine topical patch	\$1,065
2012	4Q (Dec)	<i>Atacand</i> [®] and <i>Atacand</i> [®] HCT [®] (16/12.5 and	candesartan and candesartan/	Atacand: \$157 Atacand HCT: \$73

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		32/12.5 strengths)	hydrochlorothiazide	
2012	4Q (Dec)	<i>Evoxac</i> [®]	cevimeline	\$39
2012	4Q (Dec)	<i>Maxalt</i> [®] and <i>Maxalt-MLT</i> [®]	rizatriptan	Maxalt: \$272 Maxalt-MLT: \$229
2012	4Q (Dec)	<i>Actoplus Met</i> [®]	pioglitazone/ metformin	\$402
2013	1Q (Jan)	<i>Opana</i> [®] ER	oxymorphone extended-release tablet (previously approved, not launched 6/10)	\$269
2013	1Q (Jan)	<i>Zometa</i> [®]	zoledronic acid injection	\$5
2013	1Q (Mar)	<i>Lovaza</i> [®]	omega-3-acid ethyl esters	\$655
2013	1Q (Mar)	<i>Valcyte</i> [®]	valganciclovir	\$188
2013	2Q (May)	<i>Zomig</i> [®]	zolmitriptan	\$166
2013	2Q (Jun)	<i>Allegra-D</i> [®] 24 hr	fexofenadine/ pseudoephedrine	\$172
2013	2Q (Jun)	<i>Fosamax Plus D</i> [™]	alendronate / cholecalciferol	\$123
2013	2Q (Jun)	<i>Vivelle-DOT</i> [®]	estradiol extended- release film	\$174
2013	2Q (Jun)	<i>Rilutek</i> [®]	riluzole (generic approved, not launched 1/03)	\$35
2013	3Q (Aug)	<i>Temodar</i> ^{®6}	temozolomide (generic approved, not launched 3/10)	\$205
2013	3Q (Sep)	<i>Niaspan</i> [®]	niacin extended- release tablet	\$765
2013	3Q (Sep)	<i>Advicor</i> [®]	lovastatin/niacin	\$80
2013	4Q (Nov)	<i>AcipHex</i> [®]	rabeprazole (tablets approved but not launched 2/07)	\$1,160
2013	4Q (Dec)	<i>Cymbalta</i> [®]	duloxetine	\$2,621
2014	1Q (Jan)	<i>Rapamune</i> [®]	sirolimus	\$141

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2014	1Q (Jan)	<i>Micardis[®] and Micardis[®] HCT</i>	telmisartan and telmisartan/ hydrochlorothiazide	Micardis: \$201 Micardis HCT: \$198
2014	1Q (Jan)	<i>Loestrin[®] 24 Fe⁷</i>	ethinyl estradiol/ norethindrone	\$345
2014	1Q (Jan)	<i>Asacol[®]</i>	mesalamine delayed- release tablet	\$541
2014	1Q (Feb)	<i>Renagel[®]</i>	sevelamer	\$322
2014	1Q (Mar)	<i>Evista[®]</i>	raloxifene	\$521
2014	2Q (Apr)	<i>Viracept[®]</i>	nelfinavir	\$62
2014	2Q (May)	<i>Nexium[®]</i>	esomeprazole	\$5,551
2014	2Q (May)	<i>Celebrex[®]</i>	celecoxib	\$1,581
2014	2Q (May)	<i>Lunesta[®]</i>	eszopiclone	\$805
2014	2Q (Jun)	<i>Actonel^{®8}</i>	risedronate	\$762
2014	2Q (Jun)	<i>Xeloda[®]</i>	capecitabine	\$294
2014	3Q (Aug)	<i>Teveten[®] and Teveten[®] HCT</i>	eprosartan and eprosartan/ hydrochlorothiazide	Teveten: \$7 Teveten HCT: \$5
2014	3Q (Sep)	<i>Avelox[®]</i>	moxifloxacin	\$475
2014	3Q (Sep)	<i>Vigamox[®]</i>	moxifloxacin ophthalmic solution	\$261
2014	4Q (Nov)	<i>Copaxone[®]</i>	glatiramer injection	\$442
2015	1Q (Jan)	<i>Cipro[®] HC</i>	ciprofloxacin/ hydrocortisone otic suspension	\$42
2015	1Q (Jan)	<i>Norvir[®]</i>	ritonavir	\$356
2015	1Q (Jan)	<i>Namenda[®]</i>	memantine (generic approved 4/14/10, not launched)	\$711
2015	1Q (Feb)	<i>Lumigan[®]</i>	bimatoprost ophthalmic solution	\$281
2015	1Q (Mar)	<i>Sustiva[®]</i>	efavirenz	\$166

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2015	1Q (Mar)	<i>Renvela</i> [®]	sevelamer	\$132
2015	2Q (Apr)	<i>Oxytrol</i> [®]	oxybutynin extended-release film	\$31
2015	2Q (Apr)	<i>Abilify</i> [®]	aripiprazole	\$3,583
2015	2Q (May)	<i>Zyvox</i> [®]	linezolid	\$271
2015	2Q (May)	<i>Avodart</i> [®]	dutasteride	\$461
2015	2Q (Jun)	<i>Welchol</i> [®]	colesevelam	\$271
2015	2Q (Jun)	<i>Travatan</i> [®] and <i>Travatan Z</i> [®]	travoprost ophthalmic solution	\$328
2015	3Q (Jul)	<i>Aggrenox</i> [®]	aspirin/dipyridamole extended-release capsule	\$271
2015	3Q (Jul)	<i>Gleevec</i> [®]	imatinib	\$571
2015	3Q (Aug)	<i>AndroGel</i> [®]	testosterone gel	\$652
2015	4Q (Oct)	<i>Aloxi</i> [®]	palonosetron	\$2
2015	4Q (Dec)	<i>Patanol</i> [®]	olopatadine solution	\$245
2015	4Q (Dec)	<i>Combivent</i> [®]	albuterol/ipratropium inhalation	\$649
2015	4Q (Dec)	<i>Fuzeon</i> [®]	enfuvirtide injection	\$26
2015	4Q (Dec)	<i>Coreg CR</i> [®]	carvedilol extended-release capsules	\$292
2016	2Q (May)	<i>Ortho Evra</i> [®]	ethinyl estradiol/norelgestromin transdermal system	\$130
2016	2Q (Jun)	<i>Focalin XR</i> [®]	dexmethylphenidate extended-release capsule	\$414
2016	3Q (Jul)	<i>Crestor</i> [®]	rosuvastatin calcium	\$2,626
2016	4Q (Oct)	<i>Benicar</i> [®] & <i>Benicar</i> [®] <i>HCT</i>	olmesartan & olmesartan/hydrochlorothiazide	Benicar: \$556 Benicar HCT: \$583
2016	4Q (Dec)	<i>Zetia</i> [®]	ezetimibe	\$1,111

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2017	1Q (Jan)	<i>Sandostatin</i> [®]	octreotide injection	\$39
2017	2Q (Apr)	<i>Spectracef</i> [®]	cefditoren pivoxil	\$15
2017	2Q (Apr)	<i>Vytorin</i> [®]	ezetimibe/simvastatin	\$1,233
2017	2Q (May)	<i>Relpax</i> [®]	eletriptan	\$234
2017	3Q (Sep)	<i>Cancidas</i> [®]	caspofungin injection	\$0.2
2017	4Q (Nov)	<i>Velcade</i> [®]	bortezomib injection	\$3
2018	2Q (Apr)	<i>Nasonex</i> [®]	mometasone nasal spray	\$1,098
2018	2Q (May)	<i>Cialis</i> [®]	tadalafil	\$681
2018	4Q (Oct)	<i>Nuvaring</i> [®]	ethinyl estradiol/ etonogestrel vaginal ring	\$383
2018	4Q (Oct)	<i>Sensipar</i> [®]	cinacalcet	\$371
2018	4Q (Nov)	<i>Tarceva</i> [®]	erlotinib	\$276
2019	1Q (Jan)	<i>Exelon</i> [®] Patch	rivastigmine extended- release film	\$267
2019	1Q (Jan)	<i>Hepsera</i> [®]	adefovir dipivoxil	\$99
2019	2Q (May)	<i>Vesicare</i> [®]	solifenacin	\$407
2019	2Q (Jun)	<i>Reyataz</i> [®]	atazanavir	\$616
2019	2Q (Jun)	<i>Lyrica</i> [®]	pregabalin	\$1,566
2019	4Q (Oct)	<i>Boniva</i> [®]	ibandronate	\$588
2020	2Q (Apr)	<i>Viagra</i> [®]	sildenafil	\$1,001
2020	2Q (Apr)	<i>Revlimid</i> [®]	lenalidomide	\$99
2020	2Q (May)	<i>Detrol</i> [®] LA	tolterodine	\$756
2020	2Q (Jun)	<i>Lialda</i> [®]	mesalamine delayed- release tablet	\$218

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2020	3Q (Jul)	<i>Byetta</i> [®]	exenatide injection	\$597
2020	4Q (Nov)	<i>Chantix</i> [®]	varenicline	\$493
2021	1Q (Feb)	<i>Sutent</i> [®]	sunitinib	\$138
2021	3Q (Aug)	<i>Crixivan</i> [®]	indinavir	\$9
2021	3Q (Sep)	<i>Truvada</i> [®]	tenofovir/emtricitabine	\$1,039
2023	1Q (Mar)	<i>Spiriva</i> [®]	tiotropium powder for inhalation	\$1,436
2023	4Q (Dec)	<i>Vyvanse</i> [®]	lisdexamfetamine	\$776
2023	4Q (Dec)	<i>Thalomid</i> [®]	thalidomide	\$172
2025	1Q (Jan)	<i>Trilipix</i> [®]	fenofibric acid	\$240
2026	4Q (Oct)	<i>Janumet</i> [®]	metformin/sitagliptin	\$431
2026	4Q (Oct)	<i>Januvia</i> [®]	sitagliptin	\$1,260

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

¹ Several companies have announced the settlement of patent litigation relating to Desloratadine Tablets, 5 mg (Clarinx). 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. Clarinx and Clarinx D will likely be switched to OTC availability prior to generic availability.

² 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.

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

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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 between Teva and Merck is ongoing. 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 is unenforceable, Teva may launch their generic at any time.

⁷ Warner Chilcott sued Watson for patent infringement in 2006. A settlement was reached in January 2009. Warner Chilcott sued Lupin for patent infringement 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.

⁹ Boehringer Ingelheim sued Teva/Barr for patent infringement 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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