Estimates of Expected R&D Costs

Metric	Source	Expected R&D Costs, Clinical Costs Only		Total Expected R&D Costs	
		1998	2008	1998	2008
Published estimate (2013 $)	[A]	$ 1,460.0	$ 1,460.0	$ 2,558.0	$ 2,558.0
Adjustment for genitourinary R&D costs	[B]	0.732	0.732	0.732	0.732
Adjustment for development time profile	[C]	0.672	0.672	0.938	0.938
Adjustment for inflation	[D]	0.700	0.924	0.700	0.924
Toviaz approval	[E]	10/31/2008	10/31/2008	10/31/2008	10/31/2008
Years from approval	[F]	10.5	-	10.5	-
Adjustment for present value	[G]	0.352	1.000	0.352	1.000
Expected R&D costs	[H]	$ 176.6	$ 663.5	$ 431.6	$ 1,621.4

Notes and sources:

Monetary values are in millions of $U.S.

[A] Grabowski, Henry and Ronald Hansen, "Briefing Cost of Developing a New Drug," Tufts Center for the Study of Drug Development, 11/18/2014, at 21.

Estimates based on drugs first tested in humans between 1995 and 2007.

Toviaz was authorized to test in humans 6.7 years before product approval in October 2008. See:

Moore, Thomas and Curt Furberg (2014), "Development Times, Clinical Testing, Postmarket Follow-up, and Safety Risks for the New Drugs Approved by the US Food and Drug Administration: The Class of 2008," *JAMA Intern Med.* 174(1): 90–95, at Table 1.

[B] Adjustment based on cost differences between average drug development and genitourinary drug development in:

Adams, Christopher P. and Van V. Brantner (2006), "Estimating the Cost of New Drug Development: Is It Really Worth $802 Million?," *Health Affairs* 25(2): 420–428, at 424, 426.

I note, however, that Adams and Brantner (2009) state that overall drug development costs for genitourinary drugs "may not be too different form the 'average drug.'" See:

Adams, Christopher Paul and Van Vu Brantner (2009), "Spending on New Drug Development," *Health Economics* 19(2): 130–141, at 140.

[C] Adjustment based on differences between the representative development time profile for products in the study and the development time profile for Toviaz.

The representative development time profile for products in the study is 96.8 months from clinical start to approval, and 128 months from synthesis to approval. See:

Grabowski, Henry and Ronald Hansen, "Briefing Cost of Developing a New Drug," Tufts Center for the Study of Drug Development, 11/18/2014, at 18.

The first patent application pertaining to Toviaz was filed in 1998, and Toviaz clinical trials started in June 2003. See:

Novel Derivatives of 3,3-Diphenylpropylamines, European Patent No. 0,957,073 (filed 5/12/1998, issued 11/17/1999).

ClinicalTrials.gov, Two Phase Extension Trial of SP668 to Investigate the Safety and Tolerability of Sustained Release Fesoterodine in Subjects with Overactive Bladder: A Double-Blind Phase Folowed by an Open-Label Extension Phase, https://www.clinicaltrials.gov/ct2/show/NCT00220389?term=fesoterodine&rank=50 (accessed 1/21/2016).

[D] = 1 / (CPI for 2013 / CPI for specified year (column)) from Exhibit 1049.

[E] FDA Approval Letter, NDA 22-030, 10/31/2008.

[F] = Date of [E] – (5/12/1998 or 10/31/2008).

[G] = 1 / (1 + 10.5%)^[F]. See notes and sources in Exhibit 1045 and Exhibit 1046.

[H] = [A] × [B] × [C] × [D] × [G].