

Metabolic

Metabolic products—for diabetes, obesity and hypothyroidism—are a \$19.5-billion category, with oral and injectable diabetes treatments representing the lion's share. The rising number of people with type 2 diabetes, fueled by obesity, is expected to drive growth in this market, **Marc Iskowitz** finds

At the intersection between obesity and diabetes lies an expanding market. About a third of Americans are obese, according to a 2010 *JAMA* study, and 90% of diabetes cases are type 2, which is linked to obesity, among other risk factors. The World Health Organization estimates that the number of diabetics will reach 366 million by 2030. As these problems worsen, the market for anti-diabetes therapies, up 13% in 2009, is expected to double in size in eight years.

Among adults with diagnosed diabetes (type 1 or type 2), 57% take oral medications only, according to the CDC. Takeda's Actos (#1, US) and Merck's Januvia (#3, US), both members of the thiazolidinedione (TZD) class, dominate the oral market for type 2 diabetes drugs, with \$3.2 billion and \$1.5 billion in US wholesale acquisition cost sales last year, respectively (see chart).

GlaxoSmithKline's Avandia (#10, US), another TZD, has been in sales freefall since being linked to cardiovascular problems in 2007. At press time, an FDA advisory panel was slated to debate its heart safety again following newly released findings. The second class of oral diabetes drugs, DPP-IV inhibitors, features Januvia and Onglyza, a DPP-IV launched by AstraZeneca and Bristol-Myers Squibb.

Another 14% of diabetics take insulin only, per CDC stats, and 13% take both insulin and oral medication. Sanofi-Aventis' long-acting Lantus (#2, US), along with two short-acting insulin analogs, Novo Nordisk's NovoLog (#4, US) and Eli Lilly's Humalog (#6, US), are the leaders in this injectable class. These products have been paired with discrete, pen-sized drug-delivery devices. "With those innova-

tions, Humalog continues to grow significantly even after 15 years on the market," Matthew Beebe, global commercialization leader for Lilly's diabetes portfolio, tells *MM&M*. Diabetes drug marketers, while paring back promotional spend, are spreading it out more. Sanofi launched a DTC

campaign to promote the SoloSTAR insulin pen for its Lantus franchise, using TV, print, online and social media. "We intend to remain active in using multiple communication vehicles to get education into the hands of those in the diabetes community that [this] can help the most," says Angela Moskow, VP insulins franchise marketing, Sanofi-Aventis US.

On the pipeline front, Lilly is testing a once-weekly version of its GLP-1 for type 2 diabetes, Byetta (#9, US). Lilly thinks the drug, Bydureon, will gain more widespread use among PCPs than Byetta, a twice-daily injectable. It will have competition. NovoNordisk this year launched a once-daily GLP-1, Victoza, and uptake, has been strong. Two other GLP-1s are being tested—GlaxoSmithKline's/Human Genome Science's Syncria and Roche's taspoglutide, but those may be falling by the wayside. Credit Suisse analyst Catherine Arnold has noted that, while Victoza will take significant share from Byetta, "Bydureon's once-weekly dosing and lower nausea rates should allow it to become the leading GLP-1 by 2012-2013."

Also on the horizon, MannKind is testing an inhaled insulin device, and a new class, called SGLT2s, is making progress. "It's a very exciting time for diabetes," observes Ben Weintraub, PhD, director of research, Wolters Kluwer Pharma Solutions. "Diabetes care is entering the same sort of era cardiovascular disease has enjoyed the last decade—lots of treatment options, and you can mix and match to find the best one for a patient."

The scarcity of obesity agents in development promises far fewer options. While pharma says it's targeting weight loss, the tendency of diet drugs to harm the heart and lungs has made industry skiddish. Still, Eisai made a big bet last month when it signed a multi-million dollar deal with Arena Pharmaceuticals for the right to sell Arena's lorcaserin weight-loss pill, if approved. Two other agents are hoping for FDA approval, Orexigen's Contrave and Vivus' Qnexa. "We think there will be some activity, either partnerships or acquisitions, around the FDA review of these drugs [December for Contrave and October for Qnexa]," says Weintraub, adding that all three are likely to remain niche drugs. ■

This is the fourth in a series of bi-monthly features examining different therapeutic categories. The next installment will be October's focus on oncology.



TOP 40 METABOLIC PRODUCTS, 2009

Category leaders, ranked by 2009 US sales, and their media spend

Rank	Product	Manufacturer	US sales dollars (millions)*	% change vs. prior 12 mos.	TRx count (thousands)	TRx % change vs. prior 12 mos.	US media spend dollars (thousands)**	Media spend % change vs. prior 12 mos.
1	Actos	Takeda	\$3,167.40	8.61%	13,363.20	-3.5%	\$216.90	-95.1%
2	Lantus	Sanofi-Aventis	\$2,070.60	10.25%	10,380.20	-4.9%	\$7,535.00	-39.5%
3	Januvia	Merck	\$1,486.70	31.56%	6,540.60	16.3%	\$30,888.80	-64.1%
4	NovoLog	Novo Nordisk	\$1,408.10	30.12%	4,617.70	12.6%	\$0.00	NA
5	Metformin HCL	Generic	\$1,146.20	-1.37%	49,809.40	5.9%	\$0.00	NA
6	Humalog	Eli Lilly	\$1,111.50	21.79%	4,607.90	6.2%	\$2,977.80	-31.6%
7	Synthroid	Abbott	\$767.50	1.88%	27,097.40	-4.1%	\$18.80	>999.9%
8	Lantus SoloSTAR	Sanofi-Aventis	\$763.60	97.81%	3,359.90	44.9%	\$102.70	-82.9%
9	Byetta	Lilly/Amylin	\$727.40	-2.49%	2,492.60	-18.2%	\$3,263.10	-32.6%
10	Avandia	GlaxoSmithKline	\$541.80	-17.96%	2,578.60	-32.0%	\$2.40	-99.8%
11	Levemir	Novo Nordisk	\$500.70	61.13%	2,201.20	30.1%	\$587.10	>999.9%
12	Janumet	Merck	\$492.60	64.01%	2,451.40	32.4%	\$2,645.30	17.9%
13	Levothyroxine sodium	Generic	\$469.90	13.13%	66,374.20	7.8%	\$0.00	NA
14	NovoLog mix 70-30	Novo Nordisk	\$449.60	17.73%	1,596.70	3.2%	\$0.00	NA
15	ACTOplus met	Takeda	\$438.50	17.14%	1,983.10	3.8%	\$0.00	NA
16	Humalog mix 75-25	Eli Lilly	\$286.30	12.56%	1,081.60	-0.7%	\$0.00	NA
17	Novolin 70-30	Novo Nordisk	\$257.70	0.16%	1,186.30	-11.0%	\$0.00	NA
18	Avandamet	GlaxoSmithKline	\$231.80	-2.61%	1,172.40	-13.9%	\$0.00	NA
19	Metformin HCL ER	Generic	\$231.10	1.02%	9,213.50	3.8%	\$0.00	NA
20	Prandin	Novo Nordisk	\$204.80	13.43%	976.20	-3.4%	\$0.00	NA
21	Novolin N	Novo Nordisk	\$204.60	-6.99%	689.10	-11.7%	\$0.00	NA
22	Humulin 70-30	Eli Lilly	\$191.30	1.28%	1,762.50	-10.8%	\$0.00	NA
23	Novolin R	Novo Nordisk	\$189.20	2.25%	455.60	-1.4%	\$0.00	NA
24	Humulin N	Eli Lilly	\$180.80	-2.04%	2,005.90	-13.1%	\$0.00	NA
25	Glyburide	Generic	\$175.80	-2.68%	8,958.40	-4.1%	\$0.00	NA
26	Glyburide-Metformin HCL	Generic	\$172.30	-16.39%	4,686.40	-10.0%	\$0.00	NA
27	Glimepiride	Generic	\$147.50	6.57%	10,445.90	5.9%	\$0.00	NA
28	Phentermine HCL	Generic	\$126.80	9.70%	6,809.60	11.9%	\$0.00	NA
29	Humulin R	Eli Lilly	\$122.60	18.22%	1,031.50	-4.5%	\$54.50	NA
30	Levoxyl	King	\$121.90	-7.54%	6,960.20	-16.9%	\$0.00	NA
31	Glipizide	Generic	\$100.80	-16.18%	8,675.80	4.1%	\$0.00	NA
32	Starlix	Novartis	\$97.30	-19.41%	621.50	-38.0%	\$0.00	NA
33	Glipizide ER	Generic	\$74.20	-9.67%	4,885.20	-10.5%	\$0.00	NA
34	Apidra	Sanofi-Aventis	\$70.90	15.78%	298.80	0.3%	\$57.90	646.1%
35	Glipizide XL	Generic	\$70.20	-4.31%	3,462.90	-2.0%	\$0.00	NA
36	Fortamet	Andrx	\$69.40	-1.09%	334.80	-25.0%	\$0.00	NA
37	Avandaryl	SB Pharmco	\$52.90	-13.84%	287.40	-30.2%	\$0.00	NA
38	SymLinPen 120	Amylin	\$48.50	71.90%	101.40	30.9%	\$0.00	NA
39	Xenical	Roche	\$48.40	-13.03%	159.70	-42.4%	\$0.00	NA
40	Armour Thyroid	Forest	\$43.20	-12.05%	3,650.10	-11.7%	\$0.00	NA

*Integrated wholesale acquisition cost (WAC) sales

**DTC/journal spend

Note: TRx count includes retail only. List includes products FDA indicates as approved for treating diabetes, hypothyroidism and obesity.

Sources: Sales/TRx, Wolters Kluwer Pharma Solutions; media spend, SDI.