

COMPANY	DESCRIPTION	DRUG/DEVICE NAME	UPDATED INFORMATION/INDICATION(S)	MONTH
Hygieia	Diabetes mobile app	d-Nav Insulin Guidance Service	App uses proprietary insulin-titration algorithms and patients' individual blood glucose readings to provide personalized insulin adjustments	February
Medtronic	Diabetes device	Personalized Closed Loop (PCL) insulin pump system	Breakthrough designation granted for automated closed-loop system that allows personalized, real-time insulin delivery	February
Tandem Diabetes Care	Diabetes device	t:Slim X2 insulin pump	Interoperable alternate controller enabled (ACE) infusion pump insulin pump	February
Clarus Therapeutics	Oral testosterone	Jatenzo (testosterone undecanoate)	Testosterone undecanoate in an oral capsule to treat men with certain forms of hypogonadism	March
Amgen	Osteoporosis drug	Evenity (romosozumab)	Monoclonal antibody to treat osteoporosis in postmenopausal women at high risk for fracture	April
Gelesis	Weight-loss device	Plenity	Oral hydrogel therapy for adults with overweight and obesity	April
Sprout Pharmaceuticals	Sexual desire disorder drug	Addyi (flibanserin)	Update labeling to remove some alcohol use restrictions for women taking the medication for generalized hypoactive sexual desire disorder	April
AstraZeneca	Diabetes drug	Qternmet XR (dapagliflozin/saxagliptin/metformin)	Fixed-dose combinations of SGLT2 inhibitor, DPP-IV inhibitor and metformin for treatment of type 2 diabetes	May
Amag Pharmaceuticals	Sexual desire disorder drug	Vyleesi (bremelanotide)	Melanocortin receptor agonist indicated for treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder	June
Senseonics	Diabetes device	Eversense CGM	Received nonadjunctive device status allowing users to use this implantable device as a replacement for finger sticks	June
Lilly	Diabetes drug	Baqsimi (nasal glucagon)	First nasal glucagon powder for the emergency treatment of severe hypoglycemia in children and adults with diabetes	July
Insulet	Diabetes device	Omnipod DASH	Cleared as an ACE infusion pump	September
Janssen	Diabetes drug	Invokana (canagliflozin)	Expanded indication for the SGLT2 inhibitor to reduce risks for end-stage renal disease, worsening of kidney function, cardiovascular death and hospitalization for heart failure among adults with type 2 diabetes and diabetic kidney disease	September
Novo Nordisk	Diabetes drug	Rybelsus (oral semaglutide)	First noninjectable GLP-1 receptor agonist for the treatment of type 2 diabetes	September
Xeris	Diabetes drug	Gvoke (glucagon)	Liquid glucagon stable at room temperature with delivery by syringe or autoinjector	September
AstraZeneca	Diabetes drug	Farxiga (dapagliflozin)	Expanded indication for the SGLT2 inhibitor to reduce risk for hospitalization for heart failure among adults with type 2 diabetes	October
Dexcom	Diabetes device	Dexcom G6 Pro CGM System	Professional CGM system with blinded and unblinded modes for 10-day use among patients with diabetes aged at least 2 years	October
Pfenex	Osteoporosis medication	PF708	Follow-on biologic to teriparatide injection (Forteo, Eli Lilly) for treatment of osteoporosis among patients at high risk for fracture	October
Medicines360	Hormonal contraception	Liletta (levonorgestrel-releasing intrauterine system)	Hormone-releasing intrauterine device for the prevention of pregnancy for a maximum duration of 6 years	October
Novo Nordisk	Diabetes drug	Fiasp (insulin aspart injection 100 U/mL)	Expanded indication for the rapid-acting insulin to be used in insulin pumps	October
Tandem Diabetes Care	Diabetes device	Control-IQ interoperable, automated insulin dosing algorithm	First dosing controller that can be used with other interoperable diabetes devices, allowing for a customizable automated insulin delivery system	December
Sanofi	Diabetes drug	Toujeo (insulin glargine injection 300 U/mL)	Expanded indication for use in children aged 6 years and older with diabetes	December