

Emerging Therapeutics

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Prepare for formulary changes and upcoming clinical decisions by understanding market trends and the current pipeline.

Top Pipeline Trends:

1. **Higher costs** associated with both traditional and specialty products
2. **More medications being approved** by the FDA year-over-year and more medications **coming to market sooner** than anticipated
3. Manufacturers earning **special FDA designations** such as fast track, breakthrough, priority review, and accelerated approval, more often
4. **Orphan drug approvals** (medications for diseases affecting fewer than 200,000 Americans) steadily increasing since the year 2000

The table on the next page provides the current top 10 traditional and specialty pipeline drugs, as of March 2026. The drug pipeline contains all medications in development, either being studied for first-time approval or expanded indications.

Product (Manufacturer)	Key Attributes	Expected Competition	Comments
Navepegritide - Yuviwel (Ascendis Pharma)	<ul style="list-style-type: none"> Prodrug for C-type natriuretic peptide to stimulate bone growth Once-weekly SQ Better side effect profile than competition 	Voxzogo	<ul style="list-style-type: none"> FDA accelerated approval on 2/27/2026 Launch expected 2Q2026
Ulixacaltamide (Praxis Precision Medicines)	<ul style="list-style-type: none"> Pan-T-type calcium channel blocker Indicated for patients with essential tremor Oral 	Sutsuvo	PDUFA late 2026
Tegoprazan (Braintree/Sebela Pharmaceuticals)	<ul style="list-style-type: none"> Novel potassium-competitive acid blocker for treatment of gastroesophageal reflux disease (GERD) Oral 	Voquezna	PDUFA 11/12/2026
Oveporexton (Takeda)	<ul style="list-style-type: none"> First in class orexin receptor 2 selective agonist for narcolepsy type 1 Oral 	First in class, but other standard of care: Xyrem, Lumryz, Wakix	PDUFA 3Q2026
Veligrotug (Viridian Therapeutics)	<ul style="list-style-type: none"> Humanized Monoclonal Antibody directed against the IGF-1 receptor For treatment of patients with chronic thyroid eye disease IV 	Tepezza	PDUFA 06/30/2026
Tvidenofusp alfa (Denali Therapeutics)	<ul style="list-style-type: none"> Recombinant form of iduronate 2-sulfatase enzyme For treatment of Hunter Syndrome IV 	Regenxbio	PDUFA 04/05/2026
Golimumab biosimilar (Alvotech)	<ul style="list-style-type: none"> Biosimilar to Simponi/Aria Inhibits tumor necrosis factor alpha For treatment of inflammatory conditions 	Biosimilar being developed by Bio-Thera	PDUFA 2026
Insulin Lispro biosimilar (Sandoz/Gan & Lee)	<ul style="list-style-type: none"> Biosimilar to Humalog A rapid acting insulin for treatment of diabetes 	Admelog, Lyumjev	PDUFA 2026
Omalizumab biosimilar (Kashiv Biosciences/Amneal)	<ul style="list-style-type: none"> Interchangeable biosimilar to Xolair An anti-IgE antibody for all indications including asthma, chronic rhinosinusitis with nasal polyps 	Omlyclo	PDUFA 09/26/2026
Camizestrant (AstraZeneca)	<ul style="list-style-type: none"> Selective estrogen receptor degrader for treatment of HR+/HER2- advanced or metastatic breast cancer Oral 	Orserdu, Faslodex	PDUFA mid-2026

* This represents only a subset of products in the pipeline and is not an exhaustive list of all potential approvals. Top 20 specialty and traditional pipeline documents can be provided upon request. Information is subject to change.

PDUFA: Goal date for FDA to decide whether to approve a new medication

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