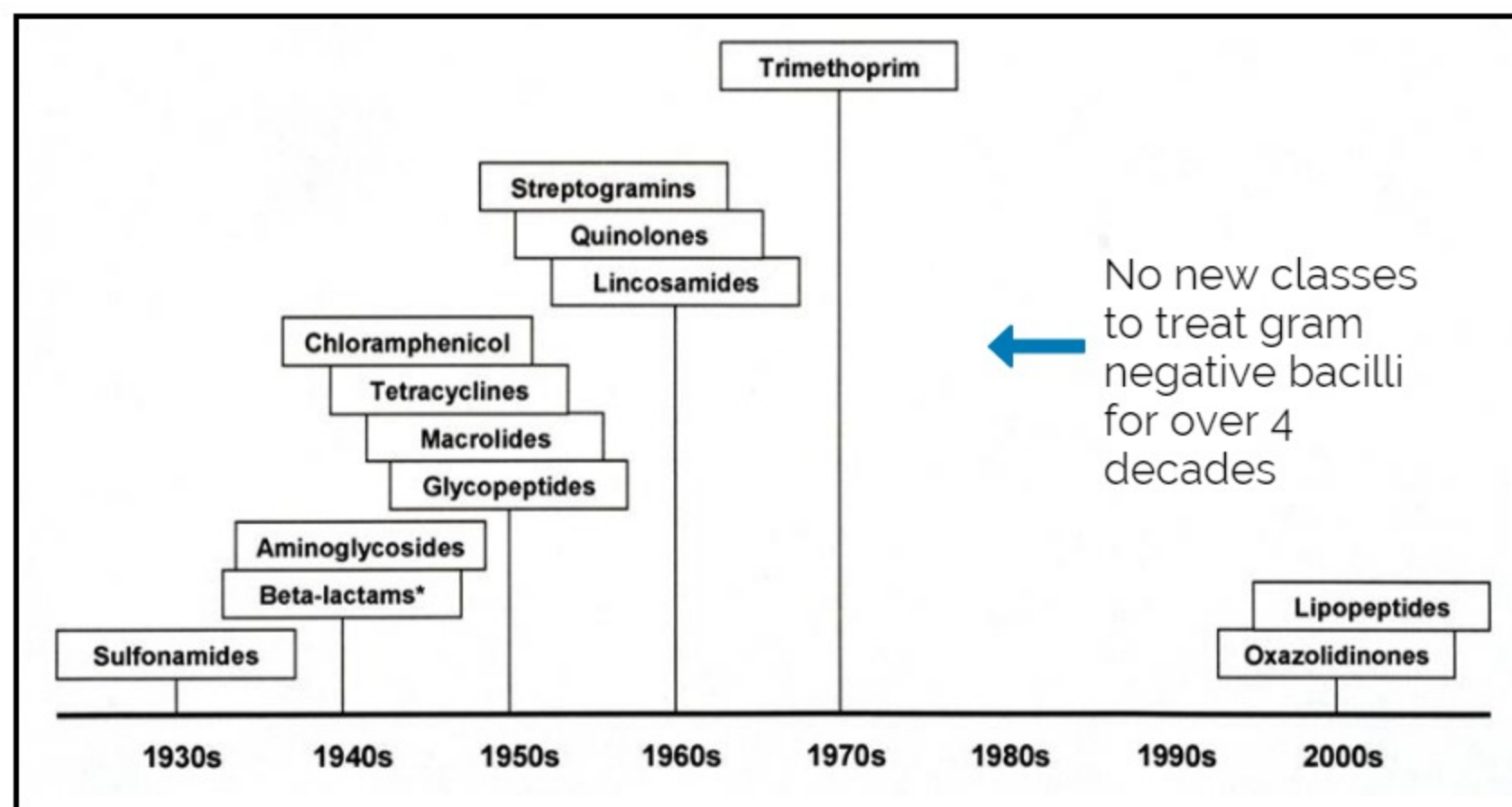


The Need for Antibiotic Incentives

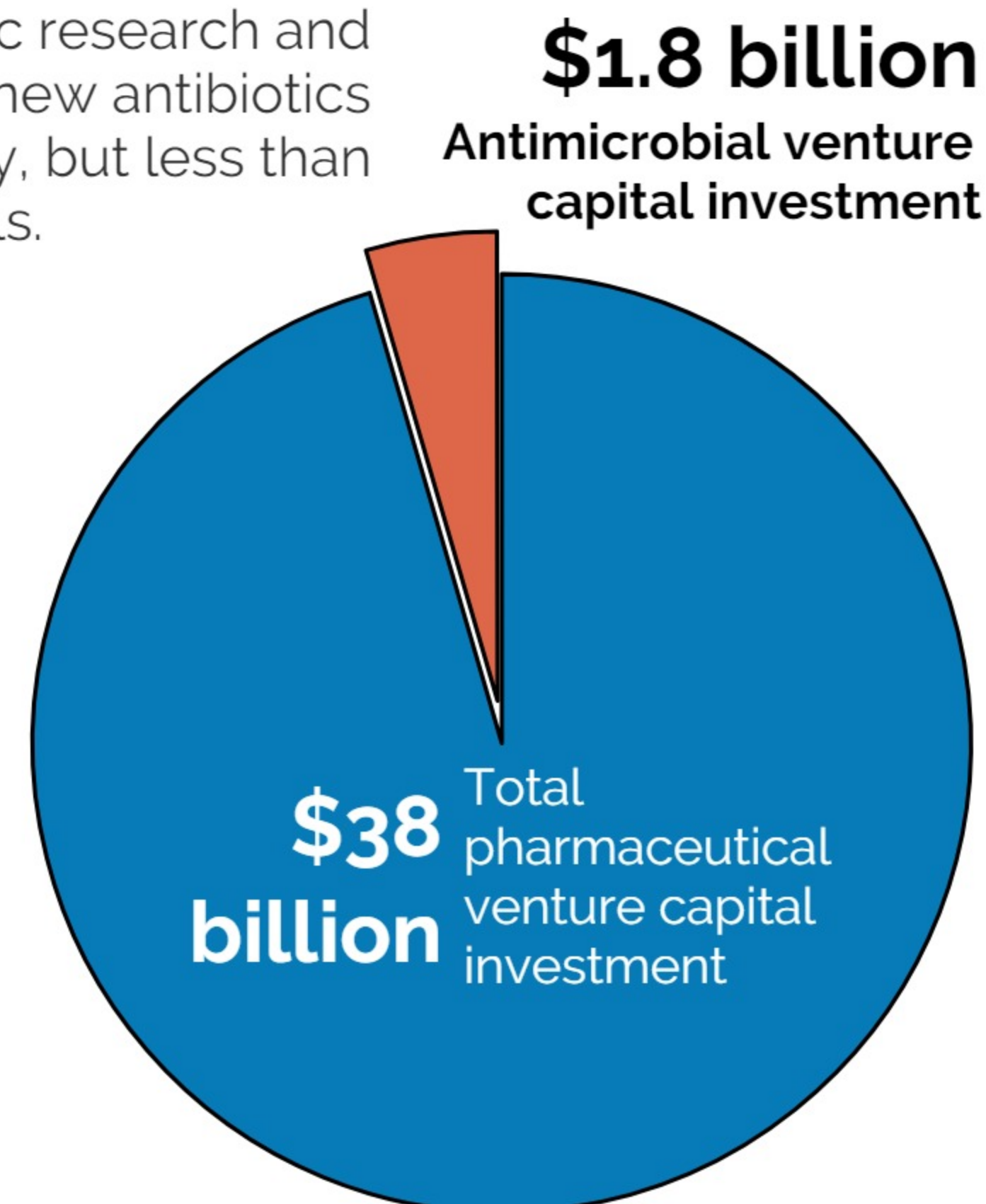
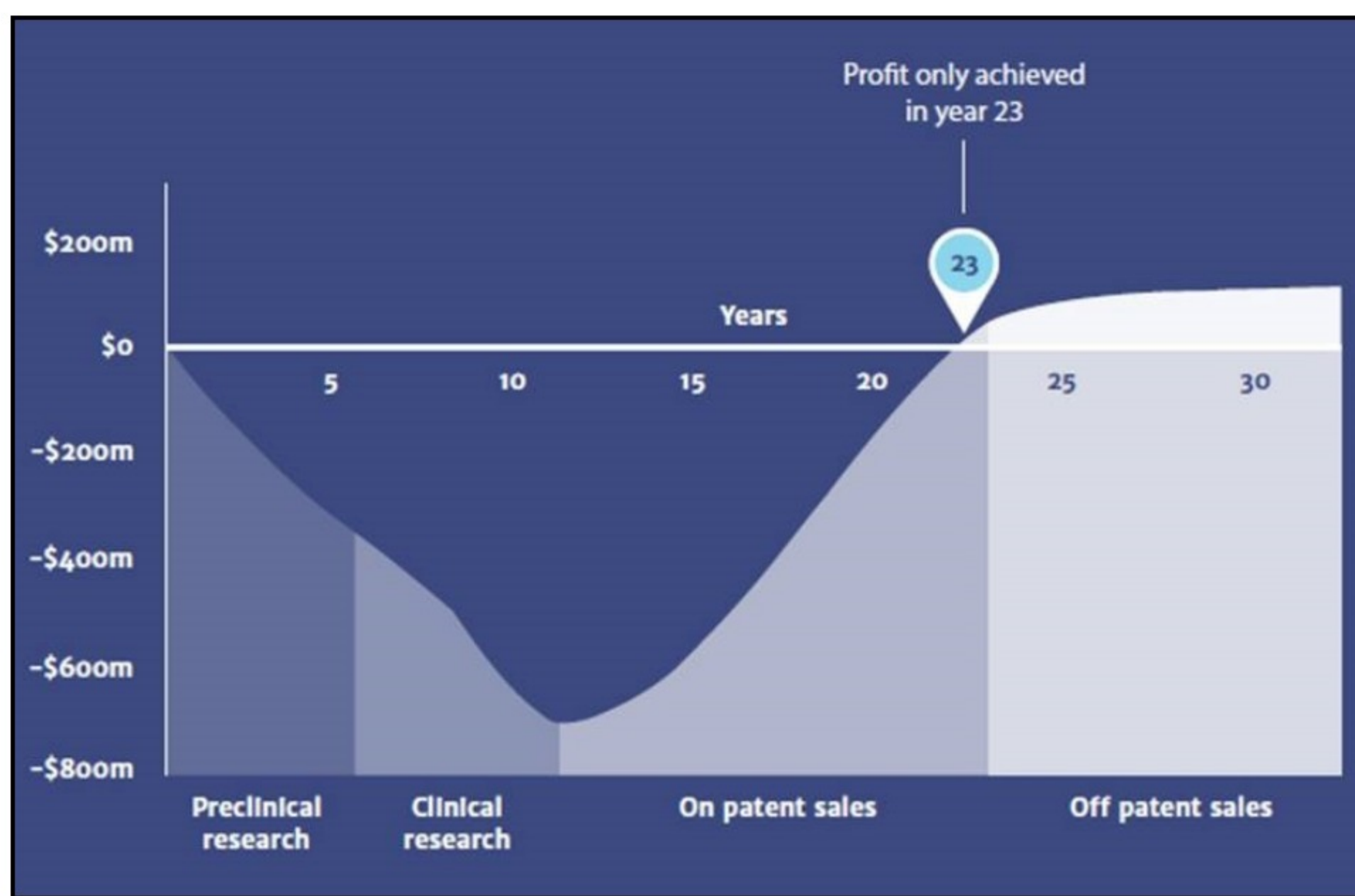
Antibiotic research and development poses unique scientific, regulatory, and economic challenges, which make antibiotic R&D riskier than R&D for other types of drugs. Even appropriate antibiotic use drives the development of resistance. As new infectious diseases threats continue to emerge, we need a robust, renewable antibiotic pipeline to meet current and future patient and public health needs. Without new incentives, we will not have urgently needed new antibiotics.

IDSA represents over 11,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), and Gram-negative bacterial infections such as *Acinetobacter baumannii*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*, emerging infections such as Middle East respiratory syndrome coronavirus (MERS-CoV), Enterovirus D68, and Ebola, and bacteria containing novel resistance mechanisms such as the New Delhi metallo-beta-lactamase (NDM) enzymes and others that make them resistant to a broad range of antibacterial drugs, including one of our most powerful classes of antibiotics, the carbapenems (carbapenem-resistant Enterobacteriaceae, or CRE).

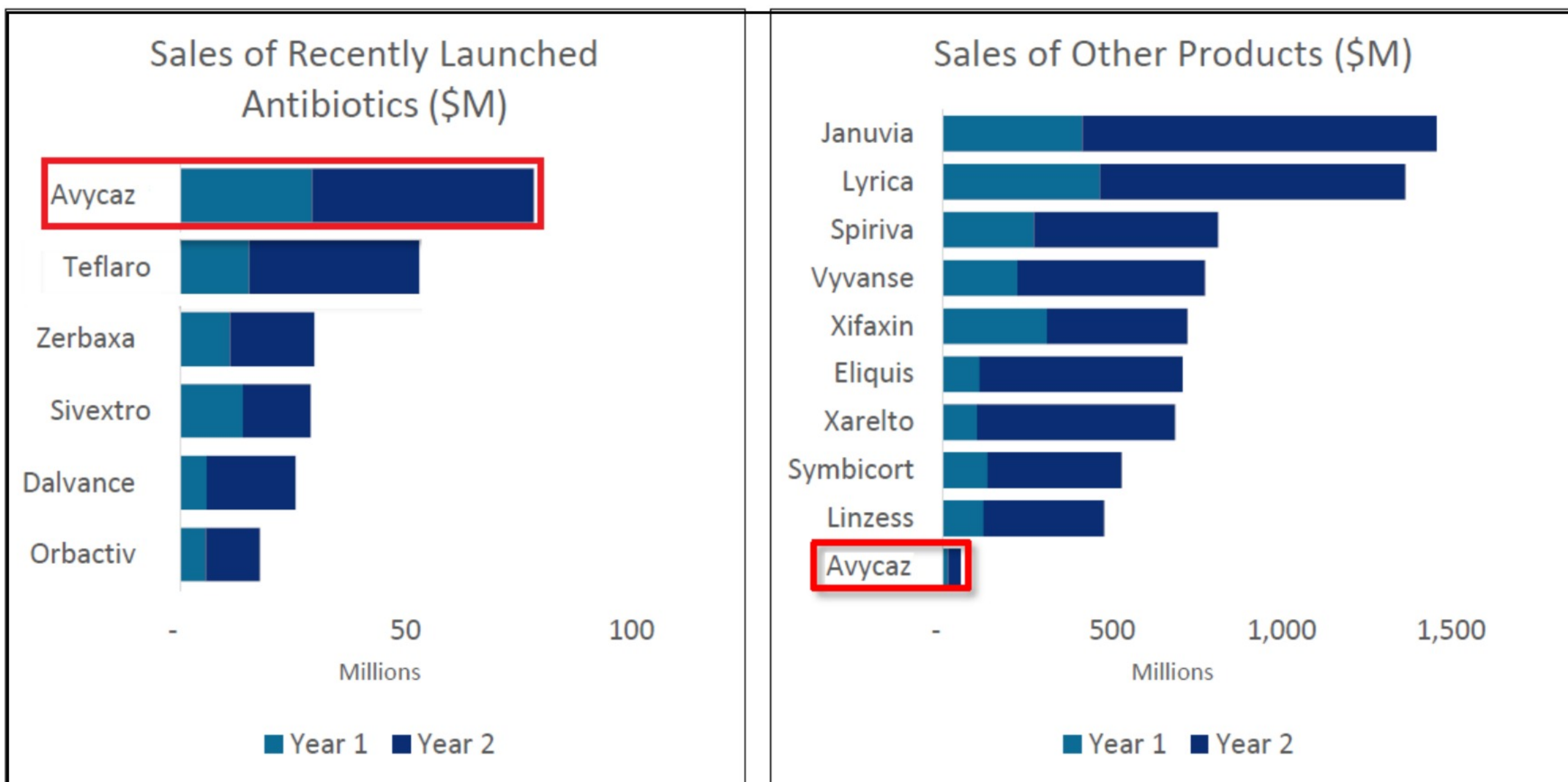


Discovery and development of new antibiotics has slowed dramatically. Every current antibiotic is a derivative of one discovered between 1900 and 1984, and the rapid increase of antibiotic resistance has led to infections that are untreatable.

Most major drug companies have reduced or quit antibiotic research and development (R&D), leaving the critical job of discovering new antibiotics to small companies with limited budgets and R&D capacity, but less than 5% of pharmaceutical venture capital goes to antimicrobials.



Antibiotics to treat resistant infections are difficult to develop. Some companies report that over a 10-year period, it took 72 lead candidate antibiotic compounds in the early discovery phase to yield one FDA-approved product; other drug types only took 15 leads to yield FDA-approval. Antibiotics also provide less financial reward for companies as they are used for a short duration and are encouraged to be held in reserve to protect against the development of resistance rather than used widely as most other drugs are once approved.



Disappointing sales of recently launched antibiotics 2 years post launch; Avycaz, a 3rd generation antibiotic indicated for complicated intra-abdominal infections (cIAI), had sales of \$75M post launch, other classes of drugs have sales between \$500M - over \$1B in sales. Many of the small companies that recently launched new antibiotics are now struggling to stay in business.

In order to address the unique challenges inherent in developing antibiotics, companies need incentives. Push incentives focus on removing barriers to developer entry by affecting the cost to the developer for investments in R&D and tend to impact the earlier stages of the development process. Pull incentives provide the promise of financial reward after a technology has been developed.