

naturally with human organism and performing vital functions such as the synthesis of vitamins, digestion, and taking part in the development of the immune system. The versatility of genes of the microbiota—microbiome—attracts the increasing interest of research community and biotech companies, as they try to develop new therapies or even find novel antibiotics by using the understanding of how our own bacteria contribute to diseases, immune responses, and the overall condition of an organism.

1.1.3 Antibiotics

The efforts for the discovery of new antibiotics have changed significantly after a long silent period. Over the last several years, the main drivers for the revived interest are the new stimuli created by the government and private organizations. Examples in the United States include the Generating Antibiotic Incentives Now (GAIN) Act of 2012 and a more recent qualified infectious disease product (QIDP) designation for antibiotics and antifungals, which provides new candidates with priority review and five additional years of market exclusivity when approved. Further support could come from the 21st Century Cures Act, approved by the House in July 2015, which includes the Antibiotic Development to Advance Patient Treatment (ADAPT) Act that permits the FDA to approve antibacterial drugs to treat serious or life-threatening infections, based on small clinical trials.

The increasing need for new antibiotics and new incentives available for business stimulate new biotech startups to emerge. Some of the recent examples include Forge Therapeutics (small molecule inhibitors of LpxC, a zinc metalloenzyme in gram-negative bacteria), Cidara Therapeutics (immunotherapy platform to fight bacterial infections), Visterra (antibody–drug conjugate therapy), Tetrphase Pharmaceuticals, Macrolide Pharmaceuticals, Iterum Therapeutics, Spero Therapeutics, and Entasis Therapeutics.

1.1.4 Artificial Intelligence

Besides the mechanical approaches to drug discovery, the functional classification of what constitutes a drug has also changed exponentially, from gene-driven therapies to artificial intelligence (AI)-based treatment modalities. We have now entered an era that was impossible to visualize even a decade ago.

The AI and machine learning advances have already been in practical use for some time in many industries, including smart cars, natural language processing (NLP), image recognition, smart online search and recommendations, fraud detection, financial trading, weather forecasting, personal and data security, and chatbots, to name a few. However, the biopharmaceutical industry is just beginning to adopt the new computational technologies, though quite rapidly.

1.1.5 Marijuana

The legalization of marijuana in the United States and the use of marijuana for recreational use in Canada have sparked a growing interest of investors, who now turn their focus to the small—but rapidly expanding—medical marijuana industry. It is estimated that the global market for medical marijuana could reach \$50 billion by 2025.