

# Global Rare Diseases Therapeutics Market - 2025 -2033

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## Abstracts

### Industry Outlook

The global rare disease therapeutics market reached US\$ 135.88 billion in 2023, with a rise of US\$ 154.64 billion in 2024, and is expected to reach US\$ 495.27 billion by 2033, growing at a CAGR of 13.8% during the forecast period 2025-2033.

The global rare diseases therapeutics market is expanding due to the growing recognition of rare genetic and chronic conditions and the focus on precision medicine. Advances in molecular diagnostics and genomics are enabling earlier and more accurate identification of rare disorders, driving demand for innovative treatments like enzyme replacement therapies, gene and cell therapies, monoclonal antibodies, and RNA-based drugs. Regulatory bodies are supporting development through orphan drug policies, expedited approvals, and financial incentives. North America is expected to dominate the market leader due to strong healthcare infrastructure and reimbursement pathways, but emerging regions show potential due to rising awareness and healthcare access.

### Market Dynamics: Drivers & Restraints

#### Driver: Rising Prevalence of Rare Genetic Disorders Globally

The rise in rare genetic disorders is driving the therapeutics market for conditions like Duchenne muscular dystrophy, spinal muscular atrophy, cystic fibrosis, and lysosomal storage diseases. The identification of previously undiagnosed patient populations and expansion of disease registries are encouraging biopharmaceutical companies to invest in niche therapies like gene therapy, enzyme replacement therapy, and RNA-based

drugs. This trend is widening the commercial scope for orphan drugs and accelerating regulatory approvals and premium pricing models, reinforcing the market's growth trajectory.

For instance, in 2024, Rare diseases affected 300 million people globally, affecting 3.5% to 5.9% of the population. 72% are genetic, with over 7000 characterized by diverse disorders. 75% affect children, with 70% onset during childhood.

### Restraint: High Treatment Cost and Limited Patient Affordability

Despite advancements in rare disease therapeutics, high treatment costs remain a significant barrier to access and market growth. The lack of generic or biosimilar alternatives further compounds the issue, as many therapies enjoy extended exclusivity under orphan drug legislation. Moreover, complex manufacturing processes for biologics and gene therapies drive up production costs, making it difficult to scale pricing models affordably. This affordability gap creates disparities in diagnosis-to-treatment timelines, limits patient reach, and challenges the long-term sustainability of rare disease care globally.

For instance, Hemgenix, a gene therapy to treat haemophilia B based on an adeno-associated virus vector, costs up to US\$3.5 million per case in the USA.

### Segmentation Analysis

The global rare disease therapeutics market is segmented based on therapy type, disease type, end user, and region.

#### Therapy Type:

The enzyme replacement therapy (ERT) from the therapy type segment the expected to have 25.51% of the rare disease therapeutics market share.

The enzyme replacement therapy (ERT) segment is experiencing significant growth in the rare diseases therapeutics market due to its clinical effectiveness in treating enzyme-deficient genetic disorders like Gaucher disease, Fabry disease, and Pompe disease. Early diagnostic advancements and newborn screening programs are facilitating timely ERT initiation. Regulatory support, R&D investments, and increased awareness among clinicians and patients are accelerating the market entry of novel enzyme therapies. Expanding reimbursement coverage in developed markets further enhances ERT's role

in rare disease management.

For instance, in May 2025, Velaglucerase-beta for injection, the first and only locally developed enzyme replacement therapy for Gaucher disease in China, has successfully advanced from concept to commercialization, marking a significant breakthrough for CANbridge Pharmaceuticals and WuXi Biologics in the R&D of innovative rare disease therapeutics in China.

## Geographical Analysis

The North America global rare disease therapeutics market was valued at 42.1% market share in 2024

North America is expected to dominate the global rare disease therapeutics market due to its developed healthcare infrastructure, heavy investment in biomedical R&D, and regulatory frameworks like the U.S. Orphan Drug Act. These incentives lower the financial risk for developing orphan drugs, while advances in genomics and personalized precision medicine accelerate the discovery and delivery of targeted treatments. Patient advocacy groups, increased disease awareness, and expanded access programs contribute to a patient-centric approach, driving demand and research momentum.

For instance, in December 2024, the U.S. Department of Health and Human Services' ARPA-H announced a new funding opportunity for the Rare Disease AI/ML for Precision Integrated Diagnostics (RAPID) program. The program aims to improve rare disease diagnostics by developing and validating AI-enabled diagnostic support systems, enabling more accurate diagnoses in less time.

Furthermore, in July 2024, the US FDA has established a rare disease innovation hub to expedite the development and approval of orphan drugs, addressing challenges in rare disease clinical trials and high development costs that have led to some therapies being dropped by companies.

Moreover, North America's robust pipeline of biologics and emerging gene therapies, supported by specialty pharmacies and cross-sector collaborations, reinforces its leadership in this niche yet high-growth segment.

## Major Players

The major players in the rare disease therapeutics market include F. Hoffmann-La Roche Ltd, Novartis AG, Pfizer Inc., Takeda Pharmaceutical Company Limited, Amgen Inc., Sanofi S.A., GlaxoSmithKline plc, Regeneron Pharmaceuticals, Inc., Biogen Inc., and Sarepta Therapeutics, among others.

### Key Developments

In February 2025, Arrowhead Pharmaceuticals expanded its We'll Get There Soon campaign, launched in November 2024, to include a dedicated educational website and a white paper on Familial Chylomicronemia Syndrome (FCS), providing essential resources and support for healthcare providers.

The global rare disease therapeutics market report delivers a detailed analysis with 70 key tables, more than 61 visually impactful figures, and 195 pages of expert insights, providing a complete view of the market landscape.

## Contents

### **1. MARKET INTRODUCTION AND SCOPE**

- 1.1. Objectives of the Report
- 1.2. Report Coverage & Definitions
- 1.3. Report Scope

### **2. EXECUTIVE INSIGHTS AND KEY TAKEAWAYS**

- 2.1. Market Highlights and Strategic Takeaways
- 2.2. Key Trends and Future Projections
- 2.3. Snippet by Therapy Type
- 2.4. Snippet by Disease Type
- 2.5. Snippet by End User
- 2.6. Snippet by Region

### **3. DYNAMICS**

- 3.1. Impacting Factors
  - 3.1.1. Drivers
    - 3.1.1.1. Increasing Government Support & Orphan Drug Designations
    - 3.1.1.2. Rising Prevalence of Rare Genetic Disorders Globally
  - 3.1.2. Restraints
    - 3.1.2.1. High Treatment Cost and Limited Patient Affordability
    - 3.1.2.2. Delayed Diagnosis and Lack of Disease Awareness
  - 3.1.3. Opportunity
    - 3.1.3.1. Advancements In Gene and RNA-Based Therapies
    - 3.1.3.2. Emerging Markets offering Untapped Growth Potential
  - 3.1.4. Impact Analysis

### **4. GLOBAL RARE DISEASE THERAPEUTICS MARKET: STRATEGIC INSIGHTS AND INDUSTRY OUTLOOK**

- 4.1. Market Leaders and Pioneers
  - 4.1.1. Emerging Pioneers and Prominent Players
  - 4.1.2. Established leaders with largest largest-selling Brand
  - 4.1.3. Market leaders with established products & Services
- 4.2. Product Developments and Breakthroughs

- 4.3. Regulatory and Reimbursement Landscape
  - 4.3.1. North America
  - 4.3.2. Europe
  - 4.3.3. Asia Pacific
  - 4.3.4. South America
  - 4.3.5. Middle East & Africa
- 4.4. Porter's Five Force Analysis
- 4.5. Supply Chain Analysis
- 4.6. Patent Analysis
- 4.7. SWOT Analysis
- 4.8. Unmet Needs and Gaps
- 4.9. Recommended Strategies for Market Entry and Expansion
- 4.10. Pricing Analysis and Price Dynamics

## **5. GLOBAL RARE DISEASE THERAPEUTICS MARKET: BY THERAPY TYPE**

- 5.1. Introduction
  - 5.1.1. Market Size Analysis and Y-o-Y Growth Analysis (%), By Therapy Type
  - 5.1.2. Market Attractiveness Index, By Therapy Type
- 5.2. Enzyme Replacement Therapy (ERT)\*
  - 5.2.1. Introduction
  - 5.2.2. Market Size Analysis and Y-o-Y Growth Analysis (%)
- 5.3. Gene Therapy
- 5.4. Monoclonal Antibodies
- 5.5. RNA-based Therapies
- 5.6. Small Molecule Drugs
- 5.7. Others

## **6. GLOBAL RARE DISEASE THERAPEUTICS MARKET: BY DISEASE TYPE**

- 6.1. Introduction
  - 6.1.1. Market Size Analysis and Y-o-Y Growth Analysis (%), By Disease Type
  - 6.1.2. Market Attractiveness Index, By Disease Type
- 6.2. Spinal Muscular Atrophy (SMA)\*
  - 6.2.1. Introduction
  - 6.2.2. Market Size Analysis and Y-o-Y Growth Analysis (%)
- 6.3. Gaucher Disease
- 6.4. Sickle Cell Disease (SCD)
- 6.5. Duchenne Muscular Dystrophy (DMD)

6.6. Fabry Disease

6.7. Others

## **7. GLOBAL RARE DISEASE THERAPEUTICS MARKET: BY END USER**

7.1. Introduction

7.1.1. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

7.1.2. Market Attractiveness Index, By End User

7.2. Hospitals\*

7.2.1. Introduction

7.2.2. Market Size Analysis and Y-o-Y Growth Analysis (%)

7.3. Specialty Centers

7.4. Others

## **8. GLOBAL RARE DISEASE THERAPEUTICS MARKET REGIONAL MARKET ANALYSIS AND GROWTH OPPORTUNITIES**

8.1. Introduction

8.1.1. Market Size Analysis and Y-o-Y Growth Analysis (%), By Region

8.1.2. Market Attractiveness Index, By Region

8.2. North America

8.2.1. Introduction

8.2.2. Key Region-Specific Dynamics

8.2.3. Market Size Analysis and Y-o-Y Growth Analysis (%), By Therapy Type

8.2.4. Market Size Analysis and Y-o-Y Growth Analysis (%), By Disease Type

8.2.5. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

8.2.6. Market Size Analysis and Y-o-Y Growth Analysis (%), By Country

8.2.6.1. U.S.

8.2.6.2. Canada

8.2.6.3. Mexico

8.3. Europe

8.3.1. Introduction

8.3.2. Key Region-Specific Dynamics

8.3.3. Market Size Analysis and Y-o-Y Growth Analysis (%), By Therapy Type

8.3.4. Market Size Analysis and Y-o-Y Growth Analysis (%), By Disease Type

8.3.5. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

8.3.6. Market Size Analysis and Y-o-Y Growth Analysis (%), By Country

8.3.6.1. Germany

8.3.6.2. U.K.

8.3.6.3. France

8.3.6.4. Spain

8.3.6.5. Italy

8.3.6.6. Rest of Europe

8.4. South America

8.4.1. Introduction

8.4.2. Key Region-Specific Dynamics

8.4.3. Market Size Analysis and Y-o-Y Growth Analysis (%), By Therapy Type

8.4.4. Market Size Analysis and Y-o-Y Growth Analysis (%), By Disease Type

8.4.5. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

8.4.6. Market Size Analysis and Y-o-Y Growth Analysis (%), By Country

8.4.6.1. Brazil

8.4.6.2. Argentina

8.4.6.3. Rest of South America

8.5. Asia-Pacific

8.5.1. Introduction

8.5.2. Key Region-Specific Dynamics

8.5.3. Market Size Analysis and Y-o-Y Growth Analysis (%), By Therapy Type

8.5.4. Market Size Analysis and Y-o-Y Growth Analysis (%), By Disease Type

8.5.5. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

8.5.6. Market Size Analysis and Y-o-Y Growth Analysis (%), By Country

8.5.6.1. China

8.5.6.2. India

8.5.6.3. Japan

8.5.6.4. South Korea

8.5.6.5. Rest of Asia-Pacific

8.6. Middle East and Africa

8.6.1. Introduction

8.6.2. Key Region-Specific Dynamics

8.6.3. Market Size Analysis and Y-o-Y Growth Analysis (%), By Therapy Type

8.6.4. Market Size Analysis and Y-o-Y Growth Analysis (%), By Disease Type

8.6.5. Market Size Analysis and Y-o-Y Growth Analysis (%), By End User

## **9. COMPETITIVE LANDSCAPE AND MARKET POSITIONING**

9.1. Competitive Overview and Key Market Players

9.2. Market Share Analysis and Positioning Matrix

9.3. Strategic Partnerships, Mergers & Acquisitions

9.4. Key Developments in Product Portfolios and Innovations

## 9.5. Company Benchmarking

## 10. COMPANY PROFILES

### 10.1. F. Hoffmann-La Roche Ltd\*

#### 10.1.1. Company Overview

#### 10.1.2. Product Portfolio

##### 10.1.2.1. Product Description

##### 10.1.2.2. Product Key Performance Indicators (KPIs)

##### 10.1.2.3. Historic and Forecasted Product Sales

##### 10.1.2.4. Product Sales Volume

#### 10.1.3. Financial Overview

##### 10.1.3.1. Company Revenue

##### 10.1.3.2. Geographical Revenue Shares

##### 10.1.3.3. Revenue Forecasts

#### 10.1.4. Key Developments

##### 10.1.4.1. Mergers & Acquisitions

##### 10.1.4.2. Key Product Development Activities

##### 10.1.4.3. Regulatory Approvals, etc.

##### 10.1.4.4. SWOT Analysis

### 10.2. Novartis AG

### 10.3. Pfizer Inc.

### 10.4. Takeda Pharmaceutical Company Limited

### 10.5. Amgen Inc.

### 10.6. Sanofi S.A.

### 10.7. GlaxoSmithKline plc

### 10.8. Regeneron Pharmaceuticals, Inc.

### 10.9. Biogen Inc.

### 10.10. Sarepta Therapeutics (LIST NOT EXHAUSTIVE )

## 11. ASSUMPTIONS AND RESEARCH METHODOLOGY

### 11.1. Data Collection Methods

### 11.2. Data Triangulation

### 11.3. Forecasting Techniques

### 11.4. Data Verification and Validation

## 12. APPENDIX

12.1. About Us and Services

12.2. Contact Us

## List Of Tables

### LIST OF TABLES

Table 1 Global Rare Diseases Therapeutics Market Value, By Therapy Type, 2025, 2029 & 2033 (US\$ Billion)

Table 2 Global Rare Diseases Therapeutics Market Value, By Disease Type, 2025, 2029 & 2033 (US\$ Billion)

Table 3 Global Rare Diseases Therapeutics Market Value, By End User, 2025, 2029 & 2033 (US\$ Billion)

Table 4 Global Rare Diseases Therapeutics Market Value, By Region, 2025, 2029 & 2033 (US\$ Billion)

Table 5 Global Rare Diseases Therapeutics Market Value, By Therapy Type, 2025, 2029 & 2033 (US\$ Billion)

Table 6 Global Rare Diseases Therapeutics Market Value, By Therapy Type, 2022-2033 (US\$ Billion)

Table 7 Global Rare Diseases Therapeutics Market Value, By Disease Type, 2025, 2029 & 2033 (US\$ Billion)

Table 8 Global Rare Diseases Therapeutics Market Value, By Disease Type, 2022-2033 (US\$ Billion)

Table 9 Global Rare Diseases Therapeutics Market Value, By End User, 2025, 2029 & 2033 (US\$ Billion)

Table 10 Global Rare Diseases Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 11 Global Rare Diseases Therapeutics Market Value, By Region, 2025, 2029 & 2033 (US\$ Billion)

Table 12 Global Rare Diseases Therapeutics Market Value, By Region, 2022-2033 (US\$ Billion)

Table 13 North America Rare Diseases Therapeutics Market Value, By Therapy Type, 2022-2033 (US\$ Billion)

Table 14 North America Rare Diseases Therapeutics Market Value, By Disease Type, 2022-2033 (US\$ Billion)

Table 15 North America Rare Diseases Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 16 North America Rare Diseases Therapeutics Market Value, By Country, 2022-2033 (US\$ Billion)

Table 17 Europe Rare Diseases Therapeutics Market Value, By Therapy Type, 2022-2033 (US\$ Billion)

Table 18 Europe Rare Diseases Therapeutics Market Value, By Disease Type,

2022-2033 (US\$ Billion)

Table 19 Europe Rare Diseases Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 20 Europe Rare Diseases Therapeutics Market Value, By Country, 2022-2033 (US\$ Billion)

Table 21 Asia-Pacific Rare Diseases Therapeutics Market Value, By Therapy Type, 2022-2033 (US\$ Billion)

Table 22 Asia-Pacific Rare Diseases Therapeutics Market Value, By Disease Type, 2022-2033 (US\$ Billion)

Table 23 Asia-Pacific Rare Diseases Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 24 Asia-Pacific Rare Diseases Therapeutics Market Value, By Country, 2022-2033 (US\$ Billion)

Table 25 South America Rare Diseases Therapeutics Market Value, By Therapy Type, 2022-2033 (US\$ Billion)

Table 26 South America Rare Diseases Therapeutics Market Value, By Disease Type, 2022-2033 (US\$ Billion)

Table 27 South America Rare Diseases Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 28 South America Rare Diseases Therapeutics Market Value, By Country, 2022-2033 (US\$ Billion)

Table 29 Middle East and Africa Rare Diseases Therapeutics Market Value, By Therapy Type, 2022-2033 (US\$ Billion)

Table 30 Middle East and Africa Rare Diseases Therapeutics Market Value, By Disease Type, 2022-2033 (US\$ Billion)

Table 31 Middle East and Africa Rare Diseases Therapeutics Market Value, By End User, 2022-2033 (US\$ Billion)

Table 32 Middle East and Africa Rare Diseases Therapeutics Market Value, By Country, 2022-2033 (US\$ Billion)

Table 33 F. Hoffmann-La Roche Ltd.: Overview

Table 34 F. Hoffmann-La Roche Ltd.: Product Portfolio

Table 35 F. Hoffmann-La Roche Ltd.: Key Developments

Table 36 Novartis AG: Overview

Table 37 Novartis AG: Product Portfolio

Table 38 Novartis AG: Key Developments

Table 39 Pfizer Inc.: Overview

Table 40 Pfizer Inc.: Product Portfolio

Table 41 Pfizer Inc.: Key Developments

Table 42 Takeda Pharmaceutical Company Limited: Overview

Table 43 Takeda Pharmaceutical Company Limited: Product Portfolio

Table 44 Takeda Pharmaceutical Company Limited: Key Developments

Table 45 Amgen Inc.: Overview

Table 46 Amgen Inc.: Product Portfolio

Table 47 Amgen Inc.: Key Developments

Table 48 Sanofi S.A.: Overview

Table 49 Sanofi S.A.: Product Portfolio

Table 50 Sanofi S.A.: Key Developments

Table 51 GlaxoSmithKline plc: Overview

Table 52 GlaxoSmithKline plc: Product Portfolio

Table 53 GlaxoSmithKline plc: Key Developments

Table 54 Regeneron Pharmaceuticals, Inc.: Overview

Table 55 Regeneron Pharmaceuticals, Inc.: Product Portfolio

Table 56 Regeneron Pharmaceuticals, Inc.: Key Developments

Table 57 Biogen Inc.: Overview

Table 58 Biogen Inc.: Product Portfolio

Table 59 Biogen Inc.: Key Developments

Table 60 Sarepta Therapeutics: Overview

Table 61 Sarepta Therapeutics: Product Portfolio

Table 62 Sarepta Therapeutics: Key Developments

## List Of Figures

### LIST OF FIGURES

Figure 1 Global Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 2 Global Rare Diseases Therapeutics Market Share, By Therapy Type, 2024 & 2033 (%)

Figure 3 Global Rare Diseases Therapeutics Market Share, By Disease Type, 2024 & 2033 (%)

Figure 4 Global Rare Diseases Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 5 Global Rare Diseases Therapeutics Market Share, By Region, 2024 & 2033 (%)

Figure 6 Global Rare Diseases Therapeutics Market Y-o-Y Growth, By Therapy Type, 2023-2033 (%)

Figure 7 Enzyme Replacement Therapy (ERT) Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 8 Gene Therapy Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 9 Monoclonal Antibodies Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 10 RNA-based Therapies Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 11 Small Molecule Drugs Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 12: Other Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 13 Global Rare Diseases Therapeutics Market Y-o-Y Growth, By Disease Type, 2023-2033 (%)

Figure 14 Spinal Muscular Atrophy (SMA) Disease Type in Global Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 15 Gaucher Disease Disease Type in Global Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 16 Sickle Cell Disease (SCD) Disease Type in Global Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 17 Duchenne Muscular Dystrophy (DMD) Disease Type in Global Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 18 Fabry Disease Disease Type in Global Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 19 Other Disease Types in Global Rare Diseases Therapeutics Market Value,

2022-2033 (US\$ Billion)

Figure 20 Global Rare Diseases Therapeutics Market Y-o-Y Growth, By End User, 2023-2033 (%)

Figure 21 Hospitals End User in Global Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 22 Speciality Centers End User in Global Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 23 Other End User in Global Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 24 Global Rare Diseases Therapeutics Market Y-o-Y Growth, By Region, 2023-2033 (%)

Figure 25 North America Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 26 North America Rare Diseases Therapeutics Market Share, By Therapy Type, 2024 & 2033 (%)

Figure 27 North America Rare Diseases Therapeutics Market Share, By Disease Type, 2024 & 2033 (%)

Figure 28 North America Rare Diseases Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 29 North America Rare Diseases Therapeutics Market Share, By Country, 2024 & 2033 (%)

Figure 30 Europe Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 31 Europe Rare Diseases Therapeutics Market Share, By Therapy Type, 2024 & 2033 (%)

Figure 32 Europe Rare Diseases Therapeutics Market Share, By Disease Type, 2024 & 2033 (%)

Figure 33 Europe Rare Diseases Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 34 Europe Rare Diseases Therapeutics Market Share, By Country, 2024 & 2033 (%)

Figure 35 Asia-Pacific Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 36 Asia-Pacific Rare Diseases Therapeutics Market Share, By Therapy Type, 2024 & 2033 (%)

Figure 37 Asia-Pacific Rare Diseases Therapeutics Market Share, By Disease Type, 2024 & 2033 (%)

Figure 38 Asia-Pacific Rare Diseases Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 39 Asia-Pacific Rare Diseases Therapeutics Market Share, By Country, 2024 &

2033 (%)

Figure 40 South America Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 41 South America Rare Diseases Therapeutics Market Share, By Therapy Type, 2024 & 2033 (%)

Figure 42 South America Rare Diseases Therapeutics Market Share, By Disease Type, 2024 & 2033 (%)

Figure 43 South America Rare Diseases Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 44 South America Rare Diseases Therapeutics Market Share, By Country, 2024 & 2033 (%)

Figure 45 Middle East and Africa Rare Diseases Therapeutics Market Value, 2022-2033 (US\$ Billion)

Figure 46 Middle East and Africa Rare Diseases Therapeutics Market Share, By Therapy Type, 2024 & 2033 (%)

Figure 47 Middle East and Africa Rare Diseases Therapeutics Market Share, By Disease Type, 2024 & 2033 (%)

Figure 48 Middle East and Africa Rare Diseases Therapeutics Market Share, By End User, 2024 & 2033 (%)

Figure 49 F. Hoffmann-La Roche Ltd.: Financials

Figure 50 Novartis AG: Financials

Figure 51 Pfizer Inc.: Financials

Figure 52 Takeda Pharmaceutical Company Limited: Financials

Figure 53 Amgen Inc.: Financials

Figure 54 Sanofi S.A.: Financials

Figure 55 GlaxoSmithKline plc: Financials

Figure 56 Regeneron Pharmaceuticals, Inc.: Financials

Figure 57 Biogen Inc.: Financials

Figure 58 Sarepta Therapeutics: Financials

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