

Business Models in Biotech & Medtech

Strategies for Innovation & Sustainable Growth

Industry Overview

Biotech Sector

Global market valued at \$1.5T+ with 10.2% CAGR projected through 2030.

Focus on therapeutics, diagnostics, and agricultural applications.

Medtech Sector

\$500B+ global market expanding at 5.6% annually through 2028.

Encompasses devices, diagnostics, digital health, and surgical equipment.

Key Business Model Categories

Product-Based Models

Drug development, medical devices, diagnostic equipment

Service-Based Models

Contract research, testing labs, clinical trials

Platform Models

Technology licensing, data platforms, software solutions

Hybrid Models

Integrated product-service combinations

Outcome-Based Models

Pay-for-performance, risk-sharing arrangements

Digital Health Models

Telehealth, AI diagnostics, wearable monitoring

Traditional Drug Development Model

- 1 Discovery & Preclinical (3-6 years)**
Target identification, lead optimization, animal testing. Cost: \$1-2M per candidate.
- 2 Clinical Trials Phase I-III (6-8 years)**
Safety, efficacy, and large-scale testing. Cost: \$50-500M per drug.
- 3 Regulatory Approval (1-2 years)**
FDA/EMA review and approval process. Cost: \$10-20M.
- 4 Commercialization & Market Access**
Manufacturing scale-up, marketing, and distribution. Ongoing investment required.

Total Investment

Average: \$2.6B per approved drug | Success rate: ~12% | Timeline: 10-15 years

Medical Device Business Model

Class I Devices

Low risk, minimal regulation. Examples: bandages, surgical instruments. Time to market: 3-12 months.

Class II Devices

Moderate risk, 510(k) clearance. Examples: infusion pumps, ultrasound. Time to market: 1-2 years.

Class III Devices

High risk, PMA required. Examples: pacemakers, heart valves. Time to market: 3-7 years.

Revenue Models

Direct Sales

One-time purchase model

Recurring Revenue

Consumables, maintenance, subscriptions

Leasing Programs

Capital equipment rentals

Service Contracts

Installation, training, support

Platform Technology Model

Core Concept

Develop proprietary technology applicable across multiple products or therapeutic areas. License platform to partners or develop internal pipeline.

Examples

Moderna: mRNA platform for vaccines and therapeutics

CRISPR Therapeutics: Gene editing technology

Illumina: Next-gen sequencing platform

Revenue Streams

Upfront licensing fees

Milestone payments

Royalties on product sales

Research collaborations

Contract Research Organization (CRO) Model

Service Offerings

Clinical Trial Management

Site selection, patient recruitment, monitoring

Data Management

Collection, analysis, regulatory submission

Regulatory Affairs

IND/NDA preparation, submissions

Laboratory Services

Bioanalytical, pharmacokinetics testing

Market Leaders

IQVIA: \$14.4B revenue, full-service CRO

Labcorp Drug Development: \$5.2B, integrated diagnostics

PPD (Thermo Fisher): \$6.9B, global reach

Pricing Models

Fixed Price: Defined scope, predictable costs

Time & Materials: Hourly/daily rates, flexible

Risk-Sharing: Performance-based compensation

Diagnostics Business Model

In Vitro Diagnostics (IVD)

Blood tests, molecular diagnostics, point-of-care testing. Market: \$85B globally.

Imaging Diagnostics

MRI, CT, ultrasound, X-ray systems. Market: \$45B globally.

Revenue Model Components

Instrument Sales

High upfront revenue, capital equipment purchases

Reagent & Consumables

Recurring revenue, high margins (60-70%)

Service Contracts

Maintenance, calibration, software updates

Razor-Razorblade Model

Subsidize instruments, profit from test volume

Digital Health & Telemedicine Model

Market Segments

Telehealth Platforms: Virtual consultations, remote monitoring

Wearable Devices: Continuous health tracking, data collection

AI Diagnostics: Image analysis, predictive algorithms

EHR Integration: Data management, interoperability

Market Growth

\$250B projected by 2028

37% CAGR from 2021-2028

Revenue Strategies

Subscription (B2C)

Monthly/annual fees for unlimited access or tiered services

Per-Visit Fee (B2C)

Pay-per-consultation model, typically \$40-80 per visit

Enterprise (B2B)

White-label solutions for health systems, employers, insurers

Data Monetization

Anonymized health data for research, pharma partnerships

Value-Based Care & Outcome Models

Paradigm Shift

Moving from fee-for-service to outcomes-based payment models that align incentives with patient health improvements.

Pay-for-Performance

Reimbursement tied to achieving specific clinical outcomes or quality metrics.

Indication-Based Pricing

Different prices for same drug based on condition treated and expected outcomes.

Risk-Sharing Agreements

Manufacturers share financial risk if treatment doesn't deliver promised results.

Subscription Models

Fixed annual fee for unlimited access to treatment (e.g., hepatitis C drugs).

Licensing & Partnership Models

Out-Licensing

Biotech grants rights to larger pharma for development, commercialization. Biotech receives upfront fees, milestones, royalties.

In-Licensing

Companies acquire external assets to expand pipeline, leverage existing infrastructure for commercialization.

Deal Structure Components

Upfront Payment

\$5M - \$500M depending on stage and potential

Development Milestones

\$50M - \$1B+ tied to clinical and regulatory achievements

Sales Milestones

Additional payments when revenue thresholds reached

Royalties

5-20% of net sales, often tiered by volume

Funding & Capital Strategy

Venture Capital

Series A-C rounds, \$5M-\$100M+

Strategic Partnerships

Corporate venture arms, co-development deals

Public Markets (IPO)

Access to large capital, liquidity for investors

Debt Financing

Venture debt, convertible notes

Typical Funding Journey

Pre-Seed / Seed (\$1-5M)

Concept validation, early research, team building

Series A (\$10-30M)

Preclinical studies, IND filing, platform development

Series B (\$30-80M)

Phase I/II trials, regulatory strategy, scale operations

Series C+ (\$50-200M)

Phase III trials, pre-commercialization, expansion

Regulatory Pathways & Market Access

Accelerated Pathways

Fast Track: Expedited FDA review for serious conditions

Breakthrough Therapy: Significant improvement over existing treatments

Orphan Drug: Incentives for rare diseases (7-year exclusivity, tax credits)

Device Classifications

510(k) Clearance: Substantially equivalent to predicate (90-day review)

De Novo: Novel low-to-moderate risk devices (150 days)

Reimbursement Strategy

Coverage Decisions

Medicare, Medicaid, private payer negotiations critical for adoption

Health Economics

Cost-effectiveness studies, QALY analysis, budget impact models

Pricing Strategy

Reference pricing, value-based agreements, patient assistance programs

Key Insight

Market access planning should begin in Phase II trials, not after approval

Emerging Trends & Future Models

Cell & Gene Therapy

Personalized treatments with one-time administration. Pricing: \$400K-\$2.8M per patient.

AI-Powered Discovery

Machine learning accelerates drug discovery, reduces R&D costs by 30-50%.

Precision Medicine Platforms

Biomarker-driven treatment selection, companion diagnostics bundled with therapeutics.

Digital Therapeutics

Software-as-medicine with clinical evidence, FDA clearance, payer reimbursement.

Decentralized Trials

Remote monitoring, direct-to-patient models reduce costs and accelerate enrollment.

3D Bioprinting

On-demand manufacturing of tissues, organs, and personalized implants.

Key Takeaways

1

Diversification is essential. Successful companies blend product, service, and platform strategies to balance risk and revenue.

2

Value-based models are accelerating. Outcome-based pricing and risk-sharing align incentives with patient results.

3

Digital integration is transformative. AI, telemedicine, and wearables create new revenue streams and improve outcomes.

4

Strategic partnerships accelerate growth. Licensing and co-development reduce capital requirements and expedite market access.

5

Market access planning is critical. Reimbursement strategy must begin early, not after regulatory approval.



Cannabics Pharmaceuticals Announced the Launch of WanaCaps XR in Colorado

Cannabics Pharmaceuticals Inc. is proud to announce that its strategic partner Wana Products...

! Yahoo Finance / Jun 22, 2015



העלה שעולה ועולה: איך הצליחה חברה של 10 עובדים לזנק ב-3,000% בארבעה חודשים

קנאביקס, שמנסה לפתח טיפולים לסרטן המבוססים על קנאביס, כבר הגיעה לשווי של 280 מיליון דולר, לאחר שבספטמבר נסחרה בשווי זעום של 5 מיליון דולר

The Marker M