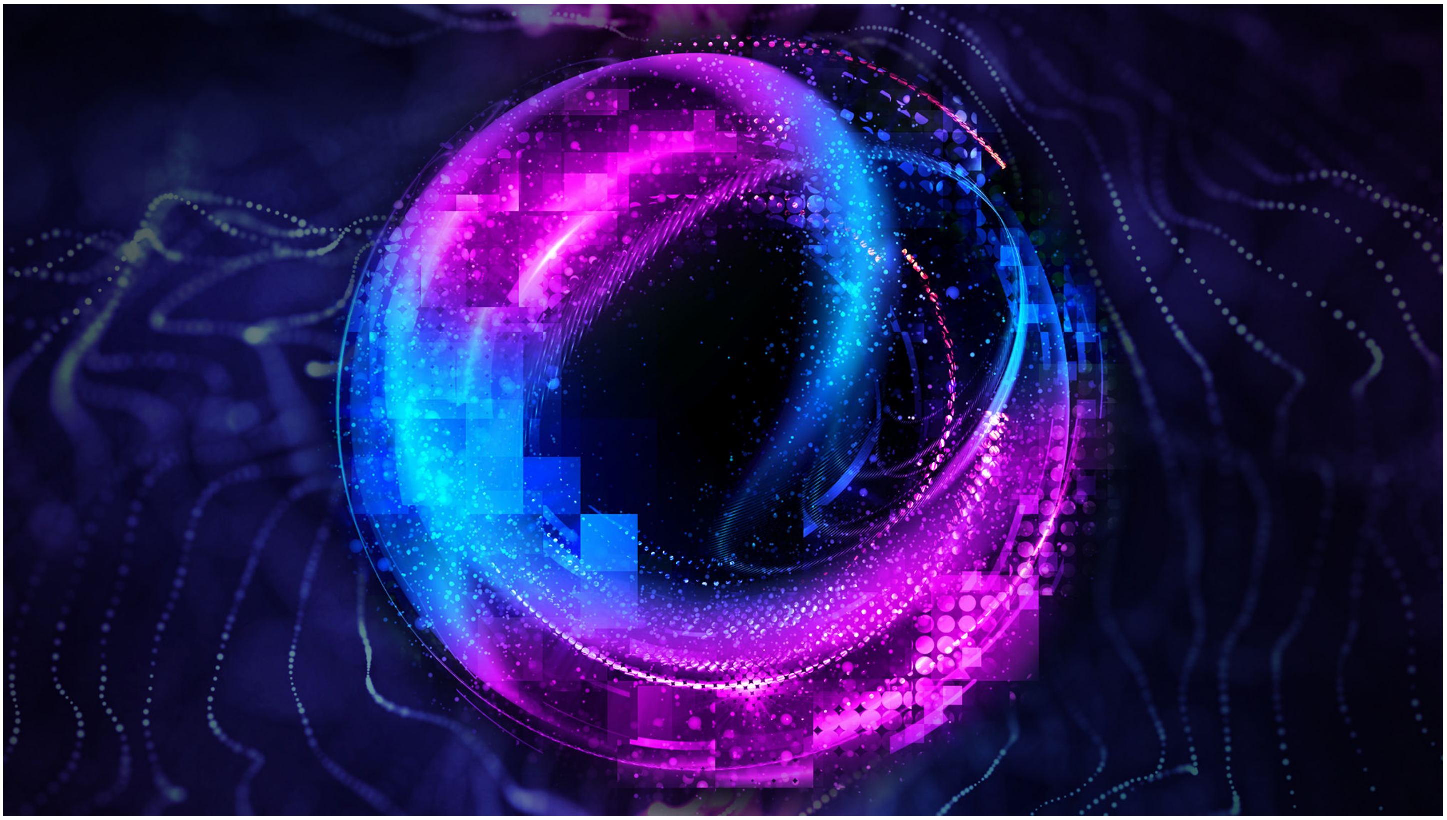

Accelerating the biotech journey

A preflight checklist of product launch considerations for the emerging biotech company

Bringing a new drug to market is a huge achievement. Early-stage companies tend to direct their attention to the resourcing, development, and enhancement of a new therapy or technology. The goal is to ensure a proper focus on the many details of the drug's safety and efficacy, which companies will have to test before submitting a new drug application to the US Food and Drug Administration (FDA) and undergoing regulatory review. All of this requires ample time, resources, and knowledge.

But development of life-saving technologies is only part of what biotech companies take on. At any point along the journey from development to commercialization, there are various key considerations across the organization that require coordination to address efficiently and effectively. As a biotech company evolves through its drug development life cycle, the finance function must also evolve and develop new capabilities to support the scaling of the broader organization.

For the finance organization, this journey from awaiting clinical data to a commercial launch or other significant company life cycle events can occur quickly. If the finance organization has not undertaken strategic planning and developed a commercialization road map based on key business milestones (e.g., NDA filing, IPO, approval, launch), the company may be woefully unprepared at the time of drug approval. Complicating matters further, there can be several scenarios under consideration due to the uniqueness of the company's technologies and complexities within the identified market, such as launch distribution channel design, commercial contracting strategies, and inventory costing methodologies. At the same time, investors expect the finance organization to have robust financial planning processed and meet the extensive financial reporting requirements of the rapidly growing company. "Turning on" these detailed and complex processes—from distribution and channel design to revenue recognition—can give pause to even the most seasoned financial professionals and sophisticated investors.

By taking a holistic view of future needs, finance teams can improve the coordination of processes and technological investments. And, similar to the clinical research, a phased approach can help biotech companies build their financial and commercial capabilities so they can validate them before going live. Along the way, companies may notice the lack of an important competency or technology—but once identified, they'll have the appropriate context for deciding how to proceed. In that spirit, here are some key finance and accounting considerations to put on any emerging biotech company's preflight checklist.

Before takeoff: Take stock of the research and development (R&D) state

Long before the time comes to commercialize, it's a good idea to take stock of the finance capabilities in place. That includes verifying that key accounting processes are established, both for R&D and for any contract research organizations (CROs) that handle trials and medical testing.

Clinical trials	Create a financial management process for clinical trials
Contractual relationships	Assess contractual relationships (e.g., collaboration and R&D funding arrangements), including milestones and deliverables
Period-end costs and accruals	Estimate costs incurred and not yet invoiced by period end, and prepare accrual calculations
Expense recognition	Map out the expense recognition process—including process flows, process narratives, and key internal controls
CRO taxes	Make tax-efficient decisions about CRO relationships, including transfer pricing and legal entity structuring
Intellectual property (IP) licensing	Determine the appropriate accounting method for IP licenses
Collaborations and joint ventures	Determine the appropriate accounting method for collaboration and joint venture agreements
FDA compliance regulations	Understand the requirements for FDA regulatory compliance and the accounting and reporting impacts
R&D taxes	Consider R&D tax issues such as tax credits, orphan drug credits, foreign taxes, and changes in ownership under Section 382

Examples of timing for product launch readiness

An emerging biotech company's finance organization typically has several important activities to accomplish in advance of a product launch.

Key finance commercialization activities and how we help

We have identified several key activities for the finance organization to undertake in advance of product launch

Drug development milestones

Phase III clinical trials → **NDA submission preparation** → **NDA submission** → **Regulatory review** → **NDA approval**

Finance activities

24 to 18 months	18 to 12 months	12 to 6 months	6 months prior to launch
Develop launch plan, including order-to-cash processes	Develop accounting framework for commercial contracting strategy	Finalize trade partner and commercial contracts	Finalize processes for managing gov't programs and commercial contracts
Perform market research	Evaluate and select third-party logistics provider	Establish roles and responsibilities for commercial finance org	Finalize processes and controls for revenue and inventory
Evaluate pricing and contracting strategy	Set up project management for the trade launch plan	Develop tools and processes for GTN estimation	Conduct pre-launch reviews with external auditors

1. Lay the groundwork for commercial accounting

(18–12 months out)

With commercialization, companies often have to scale up their accounting, finance, and market access functions significantly. This typically involves market research studies that identify the addressable market in order to estimate gross product demand. Based on these forecasts, the market access and other functions can develop to ensure patients can access the technology through their insurer. While there are many operational considerations, the following are core finance and accounting processes that are important to support a successful launch.

Commercial contracting	Develop strategies to manage and appropriately account for commercial contracts
Order to cash	Lay out the order-to-cash cycle, helping data and process integration with third-party providers
Third-party logistics	As the evaluation and selection of trade partners occurs, consider the information that will be needed and the frequency that it will be provided to ensure the accounting and finance organization and related internal controls processes can appropriately support
Contract evaluation	Establish a process for pre- and post-contract evaluations to determine profitability on a contract basis
Inventory management	Develop strategies to manage and appropriately account for inventory

2. Put a gross-to-net (GTN) accounting plan in place
(12–6 months out)

Gross-to-net is the common way of referring to the revenue deductions on the income statement between gross sales and net sales, and to the management of the reserves for these revenue deductions on the balance sheet. By the time late-stage clinical trials are over and the company is nearing launch, the GTN accounting function should be prepared for commercialization. Essential activities and tasks that should be considered at this time include the development of models and processes for estimating GTN, data governance capabilities, establishment of roles and responsibilities across the finance organization, and the design, implementation, and testing of the controls over the GTN process.

Governance and controls	Set up a structure for GTN including processes, controls, and governance
Accruals	Build models for GTN accruals based on management's estimates and key assumptions
Calculations	Create ways to verify the completeness and accuracy of the inputs to GTN calculations, including the use of key industry data Determine calculation methods for government pricing Decide how to process rebates and validate claims
Automation	Identify manual processes that could be automated Design interfaces for internal and external systems

3. Prepare for product approval (imminent)

As the company closes in on product approval, it's time to finalize the processes and internal controls supporting revenue and inventory management.

Order to cash	Finalize the order-to-cash cycle, including order management, customer invoicing, accounts receivable management, and cash application
Revenue management	Finalize internal processes for management of government pricing, commercial contracting, and rebate processing
Revenue recognition	Finalize the revenue narratives documenting revenue recognition, GTN accounting procedures, and the controls around revenue
Inventory management	Finalize the controls and procedures performed throughout the product supply chain and inventory management process
GTN accruals	Finalize activities, data requirements, methodologies, and timing for recording GTN accruals; additionally, assign final roles and responsibilities across the company to support the GTN process
External audit	Coordinate with the external financial statement auditor; as part of the financial statement review and/or audit, the external auditor will review and assess the revenue recognition and inventory costing policies in accordance with GAAP

The considerations outlined here represent just a subset of the business processes that an emerging biotech company needs to develop along its journey from discovery to commercialization. In general, finance organizations should start evaluating and determining commercialization activities around 18-plus months before product launch.

To stay on track, bear in mind that developing core finance and accounting processes doesn't necessarily mean automating or hiring third parties. Companies should consider developing strategies to acquire the competencies they need at the appropriate points along the journey. Then they can layer in processes or technology along the way. With this plan as the compass, emerging biotech companies can develop the infrastructure needed for an effective launch and beyond.

In flight: Enhancements needed for public companies

Going public via a traditional IPO or special purpose acquisition company (SPAC) merger is a step that many emerging biotech companies take during the journey to commercialization. For these companies, it's imperative to elevate people, processes, and technology to support the demanding governance and reporting environment of a public company. That means expanded capabilities that typically include:

Budgeting, forecasting, and investor relations. The financial planning and analysis and investor relations functions should be a focal point so the company can see that investors and analysts receive accurate, transparent forecasts.

Financial reporting. Finance and accounting professionals should have strong SEC reporting skills and be disciplined in meeting monthly and quarterly close and reporting deadlines.

Sarbanes-Oxley and internal controls. Preparation for Sarbanes-Oxley Section 404 compliance includes design and implementation of internal controls, controls testing for operating effectiveness, evaluation of control deficiencies, and development of remediation plans. Some companies engage an outside service provider to outsource or co-source the internal audit function.

Tax planning and strategy. Tax planning and strategy is a key element of cash management and budgeting. In addition, SPAC transactions may be accompanied by an umbrella partnership C corporation tax structure and a tax receivable agreement to allow the former target shareholders to receive certain tax benefits.

Governance. The board of directors and related committees are required to meet the governance requirements of either the New York Stock Exchange or Nasdaq, both of which require a majority of independent directors, an independent audit committee, and an independent compensation committee. They also may require an independent nominating or corporate governance committee.

Expanded information technology. A well-structured enterprise resource planning suite is needed to sustain all the business objectives discussed above. In addition, the board and chief information officer (CIO) should have an enhanced focus on cybersecurity and the protection of sensitive information.

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