

Charles River Laboratories: Turning an AMAP Goal into a Portfolio

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A five-year goal

On 16 April 2024, Charles River Laboratories International announced its Alternative Methods Advancement Project (AMAP), an initiative to develop alternatives that reduce reliance on animal testing in drug discovery and development. The company said it had invested approximately \$200 million over the prior four years and set a **five-year goal of investing an additional \$300 million**. The release described three areas: product and service development, strategic investments and partnerships, and advocacy. The goal was management's stated target; the release did not disclose a project-by-project budget, an investment schedule, expected returns, or numeric success measures. [1]

For this case, assume you have been asked to recommend how management should operationalize that five-year goal. This is a hypothetical assignment. Public information does not establish that AMAP's future spending is fully discretionary or that the goal represents a legally committed spend. Your recommendation should address portfolio emphasis, sequencing, governance and the evidence that would support continuing, scaling, changing or pausing work.

A changing scientific toolkit

New approach methodologies (NAMs) include methods such as in-vitro, in-chemico and computational approaches. The FDA Modernization Act 2.0, enacted in December 2022, updated federal nonclinical testing language and includes animal and nonanimal methods in its definition. It did not prohibit animal testing or require drug developers to adopt any one method. [2]

The scientific and adoption questions remain specific to the task. A method that can inform one defined endpoint may not replace an animal study that addresses a complex systemic question. Reproducibility, human biological relevance, transparency, technical limits and confidence among clients and regulators affect whether a method can be used. [3, 4]

Charles River already provided services using a mix of in-vivo and in-vitro methods. Its 2023 annual report described capabilities such as human stem-cell platforms, 3D in-vitro models and AI-enabled drug-design services in Discovery and Safety Assessment. In January 2024, it introduced Endosafe Trillium, an animal-free recombinant cascade reagent for bacterial endotoxin testing. The company described a client beta study and reported equivalence to its LAL method within that dataset. This is an example in a defined quality-control application; it does not demonstrate broad replacement of animal work in toxicology. [5, 6]

Investment and operating context

Management grouped AMAP activity into three pillars:

- **Products and services:** develop technologies and services that reduce animal use, and introduce modalities when considered proven.
- **Strategic investments and partnerships:** co-develop methods and work with external technology providers.
- **Advocacy:** support validation and scientific understanding, and engage with regulators and the public. [1]

The company's disclosures give little detail on how to weight these activities. They do not state which programs account for the previous \$200 million, what the additional goal would fund, whether partner agreements or current projects constrain future spending, or how management will evaluate project returns.

The 2023 Form 10-K shows a broad business with different recent operating conditions. For fiscal 2023, Charles River reported \$4.129 billion of revenue: \$792 million in Research Models and Services (RMS), \$2.616 billion in Discovery and Safety Assessment (DSA), and \$721 million in Manufacturing Solutions. Segment operating income was \$155 million, \$606 million and \$88 million, respectively. These figures describe company segments; they do not show what capital is available to AMAP or which activities have higher returns. [5]

In the same filing, management described cautious spending by biotech clients, fewer DSA proposals and longer study-start lead times. It also said large pharmaceutical clients continued investing in discovery and early-stage research. These conditions could affect demand for new methods in different ways. The company also warned that adoption may be gradual and that new technology could supplement or replace some current animal-based services. [5]

Choosing how to proceed

Charles River's stated goal creates a portfolio and governance question. An internal development emphasis could help integrate methods with existing services and retain scientific learning. A partnership emphasis could widen access to technologies and specialized expertise. A stronger evidence and adoption emphasis could improve confidence in specific use cases before broader commercialization. The pillars can coexist, but staff, projects, funding and management attention still need sequencing.

Research on NAM adoption identifies barriers across science, regulation, economics and stakeholder confidence. [3] A separate scientific-confidence framework proposes assessing fitness for purpose, human biological relevance, technical characterization, transparent data and independent review. [4] These are useful lenses for your recommendation, but they were developed for chemical safety and risk assessment and do not prescribe Charles River's AMAP process. Research on R&D outsourcing also describes tradeoffs between external access and internal control or learning; it does not estimate returns for Charles River. [7]

Your task: Recommend a governance and portfolio approach for operationalizing AMAP's five-year goal. Explain what management should build, partner for and establish through evidence and adoption work; how it should stage decisions over time; and what evidence should trigger a change in emphasis. State the assumptions you need. Do not invent project-level allocations, returns or numeric thresholds: the public sources do not provide them.

Questions for discussion

1. Which uncertainty should management resolve first: scientific performance, regulatory confidence, client adoption, partnership economics or internal capability?
2. How should Charles River balance internally developed tools with partnerships? What rights, data access or learning would matter in a partnership?
3. What evidence should be required before a tool moves from development to client use or broader commercial scale?
4. How can AMAP advance animal-use reduction while managing the possibility that existing services or assets lose value?
5. Which measures would help management learn without creating false precision or incentives to make unsupported claims?

Selected sources

1. Charles River Laboratories, [AMAP launch release](#), 16 Apr 2024, paragraphs 1-6. Supports the stated goal, prior aggregate investment and three pillars.
2. [FDA Modernization Act 2.0, Public Law 117-328, Division FF, §3209, “Animal Testing Alternatives”](#), pp. 1362-1363. Permits nonanimal methods within the statutory definition; does not prohibit animal testing or mandate NAM adoption.
3. Sewell et al. (2024), [“New approach methodologies \(NAMs\): identifying and overcoming hurdles to accelerated adoption”](#), *Toxicology Research* 13(2), tfae044. See “Technical and scientific barriers,” “Common barriers: Economic,” and “The way forward.” Narrative review focused substantially on chemical risk assessment; adoption and CRO-economics discussion is not a Charles River estimate.
4. van der Zalm et al. (2022), [“A framework for establishing scientific confidence in new approach methodologies”](#), *Archives of Toxicology* 96, 2865-2879. Framework elements at pp. 2868-2869; chemical/pesticide regulatory scope limits direct transfer.
5. Charles River Laboratories, [2023 Form 10-K](#), filed 14 Feb 2024, Item 1, pp. 7-9; Item 1A, pp. 25 and 28; MD&A, pp. 38-39; segment table, p. 49. Company-reported capabilities, risks, demand context and financial figures.
6. Charles River Laboratories, [Endosafe Trillium release](#), 29 Jan 2024, paragraphs 1-4. Company-reported product and beta-study result in a defined endotoxin-testing use case.
7. Billette de Villemeur, Scannell and Versaevel (2022), [“Biopharmaceutical R&D outsourcing: Short-term gain for long-term pain?”](#), *Drug Discovery Today* 27(11), 103333. Conceptual analysis; the cited deep read was the 2021 accepted manuscript. Useful for partnership tradeoffs, not a Charles River return estimate.