Diagnostics Commercialization Plan

Educational Guide (Not legal, regulatory, or investment advice)

Executive Summary

This guide is written for academic and research-based innovators commercializing diagnostic technologies for the first time. It is intentionally long, narrative-driven, and operationally realistic—designed to function as a handbook rather than a checklist.

Diagnostics can reach the market faster than therapeutics, but they are still regulated healthcare products that must earn clinical trust, fit into laboratory and clinical workflows, and demonstrate economic value. Many diagnostic companies fail because founders underestimate validation requirements, choose an unclear regulatory pathway, or pursue funding sources that do not match their stage.

To prevent those mistakes, this guide walks through the full commercialization path from pre-validation to launch and exit. Every section includes context, decision logic, and common failure modes, followed by actionable tables and bullet summaries you can use to plan.

Funding strategy is embedded throughout the document because financing is not a one-time event. It changes as risk is reduced—from friends and family to grants, accelerators, family offices, venture capital, and corporate partnerships.

Finally, the guide ends with three realistic endgame scenarios—launching as an LDT, obtaining FDA clearance and launching yourself, or obtaining FDA clearance and licensing to a strategic partner—along with cost and timeline expectations for each path.

Table of Contents

1. What Makes Diagnostic Commercialization Unique

Diagnostics are decision technologies. They rarely create value simply by existing; they create value by changing what someone does next—ordering a therapy, delaying a procedure, changing a care pathway, or avoiding a costly downstream event. This makes diagnostics commercialization inherently multi-stakeholder: a clinician may like the test, but a lab director must be able to run it reliably, a health system must accept workflow impact, and a payer must believe it saves money or improves outcomes.

As a result, the core commercialization problem is not only scientific performance. It is translation of performance into clinical utility and economic utility. Founders often lead with sensitivity and specificity, but buyers frequently lead with questions like: Will this change outcomes? How will this fit into our workflow? What will it replace? Who pays for it? What happens if it's wrong? These questions shape adoption far more than novelty.

Diagnostics also compete against substitutes, not just direct competitors. A new biomarker test competes with physician judgment, imaging, existing lab panels, and even "watchful waiting." If the alternative is 'do nothing' and that is culturally acceptable, your diagnostic has a higher burden to prove it changes behavior.

Regulatory decisions arrive early in diagnostics because evidence requirements depend on intended use and risk. Founders who postpone regulatory clarity often generate data that later fails to support submission or commercialization, creating expensive rework. In diagnostics, evidence is not just 'nice to have'; it is the product.

Finally, diagnostics companies often have multiple viable endgames: revenue as an LDT, scaling as an FDA-cleared product, or licensing to a strategic partner. The 'best' path depends on capital availability, operational appetite, and buyer landscape—meaning exit thinking should start earlier than most first-time founders expect. These dynamics drive nearly every downstream decision discussed in this guide:

- Value is indirect (decision-changing), not therapeutic
- Multi-stakeholder adoption (clinician, lab, payer, admin)
- Workflow fit and economics drive adoption
- Regulatory pathway shapes evidence requirements
- Multiple endgames (LDT, FDA launch, FDA license)

2. Pre-Validation & Discovery Phase (0–6 Months)

Pre-validation is where you buy clarity cheaply. The goal is not to build a company; the goal is to determine whether the diagnostic concept is worth building a company around. This phase should produce a crisp problem statement, a plausible intended use, early feasibility data, and a hypothesis about who will adopt and pay. Strong teams treat pre-validation as hypothesis testing: each experiment is designed to either increase confidence or invalidate an assumption.

Many academic diagnostics begin with a great signal in a controlled environment and then degrade when moved into real-world sample matrices, diverse populations, or operational settings. Pre-validation should therefore include early stress testing: sample variability, interference testing, and reproducibility checks across days, operators, and instruments (even in a modest way). The objective is to surface fragility early, not to hide it.

This is also the time to interview stakeholders. A founder who can explain the workflow and pain points of a clinical lab, or the decision logic of a physician in the target setting, is already ahead of most. These conversations often reshape the intended use statement and reveal whether the diagnostic is a 'must-have' or merely 'interesting.'

A disciplined pre-validation phase ends with a documented go/no-go decision. If you proceed, you should be able to articulate: (1) the target clinical decision you change, (2) the minimum evidence needed to move to the next phase, and (3) the earliest plausible commercialization route. If you cannot articulate these clearly, company formation and fundraising will likely be premature.

Funding at this stage is typically modest: internal translational funds, small foundation awards, pilot grants, or personal resources. Friends and family money may be used cautiously, but the promise should be framed around learning milestones—not commercialization certainty—because the primary output here is clarity, not revenue.

- Define clinical problem + decision changed
- Draft intended use statement (v1)
- Feasibility + robustness checks (early)
- Stakeholder interviews to validate workflow fit
- Go/No-Go decision based on evidence threshold
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Activity	Objective	Typical Duration	Deliverable
Feasibility testing	Confirm assay signal	1–2 months	Feasibility data + assay notes
Early robustness	Check repeatability/interference	2–6 weeks	Reproducibility summary
Stakeholder discovery	Validate workflow and adoption	2–6 weeks	Interview notes + insights
Competitive scan	Identify substitutes and differentiation	2–4 weeks	Differentiation statement
Go/No-Go	Decide next phase scope	2–4 weeks	Milestone plan + funding needs

3. Regulatory Strategy: FDA vs LDT

Regulatory strategy is a business strategy. It determines not only what evidence you must generate, but how fast you can reach market, how much capital you need, and which partners will take you seriously. The biggest early mistake founders make is treating regulation as something you 'deal with later.' In diagnostics, late regulatory thinking turns early data into waste because the wrong endpoints, populations, or procedures were used.

The FDA pathway (510(k), De Novo, or PMA) generally increases defensibility and buyer confidence. It can also expand market access because FDA-cleared products can be distributed broadly rather than confined to one laboratory. The tradeoff is time and cost: FDA-centered programs require robust analytical validation, well-designed clinical studies, documentation, and quality systems that many first-time founders underestimate.

The LDT pathway can be a powerful capital-efficient launch strategy. LDTs are run within a single CLIA-certified laboratory and can often reach market sooner, enabling early revenue and real-world performance learning. However, LDTs carry operational complexity (lab operations, quality management, throughput, logistics) and policy uncertainty. Founders must treat the lab as a core business asset, not a back-office detail.

A common founder-friendly approach is to plan for an LDT-first path with an FDA-ready data strategy. This means you design early validation so it can be leveraged later if you choose to pursue FDA clearance. You avoid overcommitting to a single path too early while still generating disciplined evidence.

Whichever path you choose, write down the decision logic: intended use, setting, who runs the test, distribution needs, reimbursement strategy, and target exit scenario. If you cannot connect regulatory choice to business logic, you are likely choosing based on myth rather than strategy.

- LDT: faster launch, earlier revenue, lab operations required
- FDA: broader distribution, stronger defensibility, higher cost/time
- Hybrid: LDT-first with FDA-ready evidence strategy
- Regulatory choice should align with exit goals

Decision Question	If YES, leans toward...	Why it matters
Will the test be offered outside one lab?	FDA	Distribution triggers FDA requirements
Do you need broad national rollout quickly?	FDA	Scalable commercialization
Can you operate or partner with a CLIA lab?	LDT	Provides an operational path to market
Is there a predicate test?	510(k)	Lower regulatory burden compared to De Novo
Is the use novel or high-risk?	De Novo/PMA	Greater evidence burden required

4. Clinical Validation & Study Design

Clinical validation is not academic publication. It is evidence generation for regulators, payers, partners, and future acquirers. A study that is publishable may still be commercially useless if it does not match the intended use, population, or operational setting. Founders must design validation backwards from the decision they want the test to influence.

Most validation problems come from three sources: underpowered studies, biased sampling, and mis-specified endpoints. Underpowered studies produce ambiguous results that force repetition. Biased sampling (single-site, narrow demographics, convenience samples) reduces generalizability. Mis-specified endpoints make it unclear what the test actually accomplishes. These are expensive mistakes because they are usually discovered late.

Sample sourcing is a project in and of itself. You need to understand where samples will come from, what inclusion/exclusion criteria apply, how they will be handled, and

whether you will need IRB approvals or data use agreements. Practical constraints often determine study design more than ideal scientific preferences.

For many diagnostics, a staged evidence plan is best: retrospective feasibility using banked samples, followed by a prospective observational study, followed by multi-site validation if needed. Each stage reduces risk and unlocks different funding sources. The key is to define what 'success' looks like at each stage so you can stop, pivot, or scale with confidence.

Regulatory and clinical advisors add the most value here because they prevent rework. If resources are limited, invest advisory dollars into study design quality up front rather than spending multiples later repeating a flawed study.

- Design studies backward from intended use and claims
- Define endpoints that match clinical decisions
- Plan sample sourcing early (contracts, IRB, logistics)
- Stage evidence to unlock staged funding

Validation Stage	Purpose	Typical Sample Size	Timeline	Typical Funding
Analytical validation	Performance, repeatability, limit of detection (LoD), interference	30–150	2–4 months	Pilot grants, Friends & Family (F&F)
Clinical feasibility	Directional clinical utility	50–300	3–6 months	SBIR Phase I, angel investors
Pivotal / multi-site	Generalizable evidence for FDA/commercial	300–1,000+	12–18 months	SBIR Phase II, venture capital (VC), strategic investors

PRO TIP: *If you have an academic grant, ensure you run the final validation test for the grant as you would your analytical validation as required by the FDA. This will put you one step ahead.*

5. European Regulatory Strategy: CE Mark / EU Market Access

The European pathway for in vitro diagnostics is governed by IVDR, a regulation that significantly raised the bar for evidence, documentation, and quality systems compared with the legacy directive. While this sounds daunting, IVDR is often **more navigable for startups** than the FDA pathway because it emphasizes structured technical documentation, performance evaluation, and a compliant quality management system rather than premarket submissions that can stall on precedent. For many founders, CE Marking becomes the **first achievable regulatory milestone** that validates the technology, supports distributor conversations, and creates early non-dilutive revenue opportunities.

A critical early step is correct device classification (A–D). This classification determines whether a Notified Body is required and how extensive the conformity assessment will be. Most molecular, genetic, infectious disease, and companion diagnostics fall into Class C or D, which require Notified Body review. Founders who classify incorrectly lose months in rework. Early alignment here shapes the performance evaluation plan, the depth of clinical evidence, and the structure of the technical file.

IVDR places heavy emphasis on **performance evaluation**—analytical performance, clinical performance, and scientific validity. Unlike FDA submissions that may require prospective U.S. trials, IVDR often allows a blend of literature, archived specimens, and focused clinical studies. This flexibility is a strategic advantage for early companies with limited capital. When paired with an ISO 13485 quality system, the technical documentation becomes a living regulatory asset rather than a one-time submission.

Engagement with a Notified Body is the pacing item. There is often a queue, and preparation quality determines review speed. A well-prepared technical file, risk management record, labeling package, and post-market surveillance plan can shorten review cycles by months. Once approved, the CE Mark allows commercialization across EU member states and registration in EUDAMED, providing immediate credibility with partners and investors.

Typical timelines range **9–15 months** with costs between **$75K–$150K**, substantially less than many FDA pathways. For Bootstrap founders, EU market entry is frequently the **smart first regulatory move** that funds and de-risks the U.S. strategy but be aware that it might decrease potential investors in the US as well as corporate partnerships.

Diagnostics (IVDR) – CE Mark Process

Step	Action	Details	Timeline	Typical Cost
1	Classify Device	Class A, B, C, or D based on device risk level; correct classification is crucial as it determines regulatory pathway and whether Notified Body involvement is required	1–2 weeks	$3–5K
2	Implement QMS	Establish an ISO 13485 quality management system, forming the backbone of compliance and technical documentation	2–4 months	$15–40K
3	Performance Evaluation Plan	Develop a plan addressing analytical and clinical performance requirements; includes scientific validity and supporting evidence, often leveraging literature and archived specimens	1 month	Internal
4	Technical File	Compile device description, validation data, risk management documentation, and labeling; this file is the primary regulatory submission	2–3 months	$10–25K
5	Notified Body Selection	Identify and engage a Notified Body for conformity assessment (required for Class B, C, D devices); early engagement shortens review cycles	1 month queue	—
6	Conformity Assessment	Undergo audit and documentation review by the Notified Body; quality of preparation impacts review speed	3–6 months	$25–60K
7	CE Mark Affixation	Receive approval to market device in the EU; enables commercialization and access to EUDAMED registration	Immediate	—
8	EUDAMED Registration	Register device in the EU regulatory database (EUDAMED) for official listing and transparency	2 weeks	—

6. Company Formation, Website, and Core Founder Assets

Company formation should enable execution, not consume your runway. Most diagnostic founders benefit from a simple early structure: an operating entity (often an LLC in the home state) and an investment-ready entity (a Delaware C Corporation) that can be activated when institutional capital is required. The specific structure depends on institutional policies, licensing needs, and fundraising plans, but the principle is the same: preserve flexibility and avoid expensive restructuring later.

If your technology originates at a university or hospital, you must align formation with IP ownership. In many cases, the institution owns the IP, and your company will obtain rights via a license. This makes early documentation critical: invention disclosures, provisional filings, and clear assignment/ownership documentation reduce confusion during licensing and fundraising.

Your website and company email are not cosmetic—they are credibility infrastructure. Grant reviewers, accelerators, and early investors routinely evaluate whether you can communicate the technology clearly without oversharing IP. A good founder website establishes scientific credibility, signals commercial readiness, and moves the right people to action (partner interest, investor calls, pilot sites).

Your executive summary and slide deck should evolve from the same core messaging. Early-stage decks often fail because they read like academic talks rather than investment narratives. Investors want clarity on problems, solutions, evidence, regulatory path, business model, and use of funds. A founder who can communicate this clearly is immediately more fundable.

Treat these founder assets as a system: the website, executive summary, deck, and one-page overview should share consistent claims and framing. Inconsistencies create doubt and slow fundraising.

- Formation: keep it simple; preserve future VC readiness
- Align company structure with IP ownership and licensing
- Website/email = credibility + conversion infrastructure
- Exec summary + deck = consistent, investor-ready narrative

PRO TIP: *Be prepared to answer this question when dealing with investors: If we give you funding, are you going to quit your academic position to run the company? Your answer can materially influence investor confidence.*

7. IP & Technology Transfer Negotiation

Licensing norms vary significantly by institution, technology transfer office, and jurisdiction. Technology transfer negotiations are often the hidden timeline killer for academic diagnostics. Many founders underestimate how long licensing takes and how much it impacts fundraising. A license that is too restrictive can reduce exit value or scare away investors; a license that is unclear can stall deals. The goal is not to 'win' against the institution—it is to create a structure that allows the technology to succeed commercially while fairly rewarding the institution.

Key terms typically include: exclusivity, field of use, sublicensing rights, equity, royalties, milestone payments, and diligence obligations. Founders should understand that royalty stacking can become a major issue if multiple patents or components are involved. Diligence clauses (development deadlines) can be problematic if your validation takes longer than expected—which it usually does.

A practical approach is to negotiate terms that preserve optionality. For example, ensure you have clear sublicensing rights if licensing to pharma is a plausible endgame. Ensure milestones are achievable with realistic funding timelines. If you cannot meet diligence obligations without VC funding, your license should not assume VC funding will happen on a specific schedule.

The best time to start licensing discussions is early—often during pre-validation—so that by the time you seek meaningful grants or seed investment, you can show progress and clarity. Investors routinely ask: Do you control the IP? If the answer is uncertain, funding slows down.

If needed, use expert advisors selectively here. A few hours of experienced input can prevent years of downstream pain.

License Term	Why it matters	Founder-friendly target (typical)
Exclusivity	Protects commercialization path	Exclusive in defined field of use
Sublicensing rights	Enables pharma licensing exits	Explicitly permitted
Royalties	Impacts margins and exit value	Moderate; avoid stacking
Milestones/diligence	Can trigger termination	Realistic, fundable timelines
Equity	Aligns institution with success	Reasonable early %

8. Funding Through Commercialization: When to Raise What

Funding is not a single event; it is a staged strategy that tracks risk reduction. Diagnostic founders should view funding sources as tools designed for different stages. Friends and family is often the first external capital, but it should be used to fund learning milestones, not scale. The goal is to reach a point where non-dilutive funding and early institutional support become realistic.

Non-dilutive funding—especially SBIR/STTR and state grants—can dramatically improve capital efficiency in diagnostics. These programs are designed for early validation and feasibility. The key is to align your specific aims with the evidence milestones that reduce risk. A common mistake is writing a grant that reflects academic curiosity rather than a commercialization plan; reviewers want to see a path to impact.

State competitions and accelerators are valuable not only for funding but for credibility, mentorship, and network access. However, accelerators vary widely in quality. The right accelerator helps clarify regulatory strategy, payer logic, and go-to-market. The wrong one burns time and forces a one-size-fits-all narrative.

Family offices and angels often become relevant when you have early evidence and a credible plan. Family offices sometimes have longer horizons and mission alignment, but they still behave like investors: they want risk reduction and a plausible return. They are not 'free money.' This is where clear milestones and disciplined use of funds matters.

Venture capital and corporate partnerships typically enter when regulatory clarity is established, and the evidence plan is de-risked. Corporate partners often care about strategic fit and evidence; VCs care about scale potential and exit outcomes. Both will scrutinize your regulatory pathway, IP position, and validation design.

PRO TIP: *Once you have set up your company and have your initial validation data, produce a one pager with data, intended use, commercialization path and estimated time for clinic ready. Research specific pharma's that would be interested in the diagnostic test, find the correct decision maker and send them an introductory email introducing yourself and the technology. Send them updates after every milestone. This is particularly important if your diagnostic is for an unmet clinical need. Forging early relationships might result in an early strategic partnership that could provide early funds and guidance. Use conferences to make these connections. This outreach should always be framed as informational and relationship-building, not a solicitation.*

Stage	Capital Source	Typical Use	Founder Mistake to Avoid
Pre-validation	Personal / translational grants	Feasibility and clarity	Overbuilding too early
Early validation	Friends & family	Pilot data, prototype, planning	Overpromising outcomes
Development	SBIR/STTR + state grants	Analytical/clinical feasibility	Academic aims vs commercialization aims
Expansion	Competitions + accelerators	Credibility and network	Joining low-fit programs
Scale validation	Angels + family offices	Larger studies, ops setup	Premature hiring
Launch/exit prep	VC + corporate partnerships	Commercialization or licensing	Unclear regulatory/exit narrative

9. Reimbursement, Pricing, and Market Access

Reimbursement is the most common reason 'good' diagnostics fail commercially. A test can be accurate, cleared, and clinically interesting, yet still struggle if no one can get paid for using it. Founders should therefore treat reimbursement strategy as an early design constraint rather than a late-stage add-on.

Market access begins with understanding who pays and why. In some cases, the payer is a commercial insurer; in others it is Medicare/Medicaid; sometimes it is a hospital budget; sometimes it is a pharma sponsor. Each payer type has different evidence expectations. If your test claims cost savings, you may need outcomes or utilization data; if it claims improved selection of therapy, you may need evidence tied to clinical pathways.

Pricing should align with value and workflow. Labs think in terms of cost per test, throughput, and complexity. Clinicians think in terms of decision usefulness. Payers think in terms of net cost impact. A founder who can articulate value in all three languages is far more likely to succeed.

Even if you do not finalize reimbursement early, you should map likely coding and payment pathways and identify what evidence is needed to support coverage. This informs what you measure during clinical validation.

A practical approach is to build a simple reimbursement hypothesis: what code pathway might apply, what your approximate price range could be, and what evidence would convince payers. Update this hypothesis as data and feedback arrive.

- Don’t wait until after validation to think about reimbursement
- Define payer and coverage logic early
- Align validation endpoints with coverage evidence needs
- Price must work for labs and payers, not just founders

10. Operational Readiness, Quality Systems, and Scaling

Operational readiness is where many diagnostic companies stumble, especially LDT-first companies. Running a lab test at research scale is not the same as running it reliably at commercial scale. Quality systems, documentation, and repeatability become business requirements, not just technical preferences.

For LDT paths, CLIA compliance and lab operations become core competencies. You must think about staffing, throughput, sample logistics, reporting, and customer support. Founders often underestimate the operational overhead and the need for systems, even when the science is strong.

For FDA paths, quality management systems (QMS) and design controls become foundational. Building these systems late is expensive and risky. It is often better to implement lightweight documentation and controls early that can mature over time.

Scaling should track validation and demand. Over-hiring before validation is a classic runway killer. Instead, use milestone-based staffing and fractional expertise. The goal is to buy capability only when it is needed.

Operational excellence also increases investor confidence. Teams that can show disciplined process, clear documentation, and measured scaling are perceived as lower risk—even if they are at an earlier stage.

Capability	LDT Focus	FDA Focus	When to Implement
Quality documentation	CLIA processes	Design controls/QMS	Early (lightweight)
Sample logistics	Critical	Important	Before any clinical study
Reporting/results	Commercial-grade	Submission-grade	During validation
Customer support	Lab clients	Broader users	Pre-launch
Scaling plan	Throughput	Manufacturing/distribution	As demand grows

11. Commercial Launch Models

Launch is not a single moment; it is a controlled transition from development to market engagement. In diagnostics, the first version of commercialization is often a carefully constrained deployment: specific sites, specific indications, and clear measurement of performance in real-world conditions.

An LDT launch emphasizes operational control and early revenue. It allows you to learn from real usage and refine workflows. The tradeoff is that you must operate the lab environment, manage quality and logistics, and handle customer relationships. This can be a strong path for founders who want capital efficiency and can build operational capability.

An FDA-cleared launch emphasizes scalability and defensibility. Once cleared, you can distribute more broadly, and strategic buyers often view FDA clearance as a major de-risking event. The tradeoff is larger upfront capital needs and longer time to first revenue.

Hybrid models exist: launch as an LDT to generate evidence and revenue, then pursue FDA clearance as you scale. This hybrid approach requires careful evidence planning so your early work supports later submission. If you 'wing it' early, you often must redo studies later.

Your launch model must match your capital structure. If you raise VC funds, you will likely be expected to scale. If you remain grant- and revenue-funded, constrained deployment may be a better fit.

- Constrained launch reduces risk and focuses learning
- LDT = speed + ops responsibility
- FDA = defensibility + capital/time
- Hybrid works only with planned evidence strategy

12. Exit Strategy Scenarios and Cost Estimates

Exit strategy should be planned early because it influences regulatory choice, evidence design, staffing, and fundraising narrative. Most diagnostic exits occur through acquisition or licensing rather than IPOs. Strategic buyers value clarity: clear intended use, clear regulatory pathway, strong IP position, and validated evidence.

There are three common strategic outcomes for diagnostics founders. The first is to retain lab space and launch as an LDT, building a revenue-generating business that can grow organically or serve as a platform for later clearance. The second is to pursue FDA clearance and build the commercial machine yourself, which can create the highest long-term valuation but requires significant capital and execution. The third is to pursue FDA clearance and license the cleared test to a strategic partner, transferring commercialization risk while capturing value.

Your cost and timeline will vary based on complexity, indication, and study design, but founders should plan with realistic ranges. Underestimating cost is the fastest way to run out of runway in diagnostics. The ranges below are intentionally conservative to avoid false confidence.

Founders should also understand what strategic buyers pay for. Buyers pay for reduced risk: clean regulatory posture, strong evidence, defensible IP, and commercial proof. Your strategy should aim to create these assets systematically.

A helpful mindset is to treat each stage as building an 'exit-ready package'—even if you intend to operate long-term. That discipline increases optionality.

Option 1: Retain Lab Space, Raise Funds, Launch as an LDT

This path prioritizes speed and capital efficiency. You retain control of lab operations, launch the test within a CLIA environment, generate early revenue, and learn from real-world use. Many founders then decide whether to pursue FDA clearance based on traction, payer feedback, and strategic interest.

Cost Category	Typical Range (LDT)
Analytical validation & assay optimization	$50K–$300K
Clinical validation (retrospective/prospective)	$200K–$1.2M
CLIA lab setup/partnering, QA, operations	$100K–$600K
Software/reporting, logistics, support	$50K–$300K
Total Estimated Cost	$500K–$2.5M

Timeline expectation: 12–24 months (faster when samples and lab access are readily available).

Recent market precedents (last 5 years)

These examples illustrate how strategic buyers and public companies value CLIA/LDT-ready assets: a combination of strong clinical evidence, an operational CLIA lab, reimbursement strategy, and a credible commercialization plan. Use them as proof-points—not promises—when you discuss exit options with advisors and investors.

Examples:

- • Illumina completed its acquisition of GRAIL in August 2021 (announced at $8B consideration). GRAIL's Galleri test has been offered through a CLIA-certified laboratory and has not been FDA cleared/approved—an example of the "LDT-first" commercialization posture in a high-profile program.
- • In 2025, MDxHealth acquired Bio-Techne's Exosome Diagnostics business (including the ExoDx Prostate test and a CLIA-certified lab) for $15M total consideration—an example of a smaller, lab-based LDT asset deal.

Source links:

- https://investor.illumina.com/news/press-release-details/2020/Illumina-to-Acquire-GRAIL-to-Launch-New-Era-of-Cancer-Detection/default.aspx
- https://www.galleri.com/lab-info
- https://mdxhealth.com/press_release/mdxhealth-announces-closing-of-exosome-diagnostics-acquisition-from-bio-techne-2/

Option 2: Retain Lab Space, Obtain FDA Clearance, and Launch Yourself

This path aims for maximum defensibility and scalable market access. The company completes FDA clearance and then builds commercialization capability (sales, marketing, partnerships, support). It can produce the highest valuation but requires disciplined execution and substantial capital.

Cost Category	Typical Range (FDA + Launch)
Analytical validation & design controls	$250K–$1.0M
Clinical studies (multi-site/pivotal)	$1.5M–$6.0M
Regulatory submission, QMS, audits	$500K–$2.5M
Launch infrastructure (sales, marketing, support)	$1.0M–$5.0M
Total Estimated Cost	$5M–$15M+

Timeline expectation: 24–48 months depending on pathway (510(k) vs De Novo) and study complexity.

Recent market precedents (last 5 years)

FDA-cleared/approved diagnostics assets can command meaningful premiums when they slot into an acquirer's installed base, menu expansion strategy, or reimbursement footprint. These examples highlight what "defensible, scalable" looks like to buyers.

Examples:

- Roche announced a definitive agreement to acquire GenMark Diagnostics in 2021 for a total transaction value of ~US$1.8B—an example of a strategic acquirer paying for an FDA-regulated molecular diagnostics platform and menu expansion.

Source links:

- https://www.roche.com/media/releases/med-cor-2021-03-15b

Option 3: Obtain FDA Clearance, Do Not Launch, License to Pharma/Strategic

This model is designed to reduce commercialization execution risk. The company creates an FDA-cleared asset with strong evidence and then licenses it to a strategic partner. This can be an attractive path when the buyer has existing commercialization channels or when the diagnostic is tightly linked to a therapy or companion diagnostic narrative.

Cost Category	Typical Range (FDA + License)
Analytical validation & design controls	$250K–$900K
Clinical studies (targeted pivotal)	$1.0M–$4.5M
Regulatory submission, QMS, audits	$400K–$2.0M
Partnering costs (BD, legal, diligence support)	$150K–$600K
Total Estimated Cost	$3M–$8M

Timeline expectation: 24–36 months, with partnering discussions often starting well before clearance.

Recent market precedents (last 5 years)

Even if you don't plan to build a commercial salesforce, you can still create a valuable asset by producing clean clinical evidence, regulatory-grade validation, and a partner-ready package (technical files, quality system evidence, and economic story). Public deal terms are often not disclosed for CDx partnerships, but there are still useful, recent examples of licensing-style monetization.

Examples:

- • In 2025, Tempus announced expanded strategic agreements with AstraZeneca and Pathos that included $200M in data licensing and model-development fees—an example of a “license the platform/data” path that can run in parallel with (or ahead of) a regulated IVD strategy.
- • Guardant Health and AstraZeneca announced a companion diagnostic collaboration in 2022 (financial terms not disclosed). This is typical for CDx partnerships: the value is real, but the economics are frequently embedded in broader drug-development programs.

Source links:

- https://www.tempus.com/news/tempus-signs-expanded-strategic-agreements-with-astrazeneca-and-pathos-to-develop-the-largest-multimodal-foundation-model-in-oncology/
- https://investors.guardanthealth.com/press-releases/press-releases/2022/Guardant-Health-Announces-Collaboration-With-AstraZeneca-to-Develop-Companion-Diagnostic-to-Identify-Patients-With-ESR1-mutated-Metastatic-Breast-Cancer/default.aspx

PRO TIP: *When assessing exit strategy and potentially successful exits use the most conservative figures for both your time estimate and costs. If the estimate is 24-48 months, use 48 months for planning. If the cost estimate is $5M-$15m, use $15M for your estimates from the start.*

Appendix A: Decision Trees

Decision Tree 1 — FDA vs LDT

1) Will the test be offered outside a single CLIA lab?
    a. If yes → FDA likely. If no → LDT may be appropriate.
2) Is broad distribution required for your business model?
    a. If yes → FDA. If no → LDT-first may work.
3) Is there a predicate?
    a. If yes → 510(k). If no → De Novo/PMA assessment.

Decision Tree 2 — Launch vs License

1) Do you have capital and appetite to commercialize?
    a. If yes → Launch. If no → License.
2) Does a strategic buyer have obvious channel fit?
    a. If yes → License value increases.
3) Is your test tied to a therapy workflow?
    a. If yes → Pharma licensing becomes more likely.

Appendix B: Stage Checklist

- Intended use statement drafted and refined
- Regulatory path selected with documented rationale
- Validation plan staged with sample sourcing mapped
- Funding plan aligned to risk reduction milestones
- IP path clear (license/assignment) and sublicensing rights understood
- Launch model chosen (LDT, FDA launch, hybrid)
- Exit narrative articulated and costed

It should be noted that this is a generic commercialization plan and each diagnostic technology is different so not all issues discussed here might be relevant or there might be other factors not discussed here. This is meant as a starting point as you assess your desire to commercialize your discovery and whether you can make the time commitment to complete the job. As you move forward you will need to customize this document to conform to your technology.

Need help with any of these stages? ***Bootstrap your Biotech*** is here for you. I offer a number of low-cost services to help you through each stage of your journey. No long-term commitments, just fast, experienced advice when you need it.

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Examples of companies, transactions, funding mechanisms, and exit outcomes are provided solely for illustrative purposes and do not represent guarantees or predictions of future performance or success.