Taking Strategic Partnerships to the Next Level: An Alternative Approach to Licensing Your Development Asset

inVentiv Health

TRANSFORMING PROMISING IDEAS INTO COMMERCIAL REALITY

Introduction

In this era of strategic development deals, inVentiv Health has significantly broadened its platform, expanded its offerings, and strengthened its commitment to support biotech and pharma clients who may be inclined to follow a traditional licensing model.

While licensing offers the certainty of upfront payments and the promise of future royalties, many early stage companies today have expressed interest in staying involved in the development of their molecules longer. They aspire to create maximum value for company founders and initial investors by maintaining more control over more of their product's life cycle.

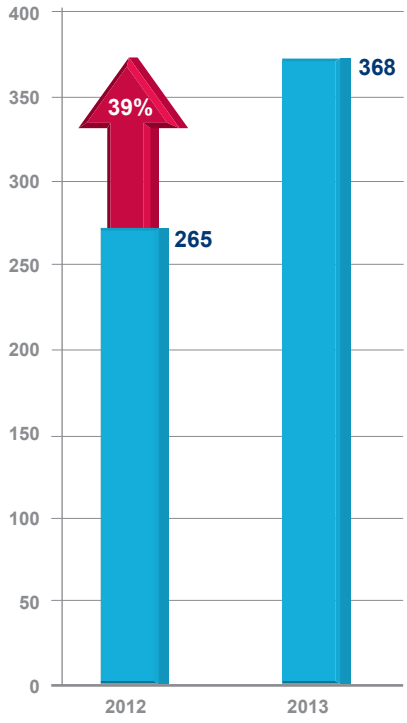
Here, we explore the benefits and drawbacks of the traditional licensing model and present new alternatives for capturing more value from your development asset.

Only inVentiv can bring you such product development flexibility through our full range of clinical, commercial, and consulting services. *(See Figure 5.)*

Figure 1.

Traditional licenses up 39% the first half of this year compared to 2012[1]

Licensing: the traditional model — but not the only model



1. See http://bit.ly/ldB2lw

The Traditional Licensing Model

For many years, the primary model for early stage companies with development assets has been to complete clinical research through whatever stage of development achieves the highest value for the company versus the investment made in its product. Depending on the nature of the drug, the best exit might fall anywhere between pre-Proof-of-Concept and Phase III.

The traditional licensing approach presents both benefits and drawbacks.

Significant benefits include:

- A pharmaceutical partnership validates your science and approach.
- Non-dilutive capital supports your pipeline development and company growth.
- You may enjoy a commercial opt-in for selected key geographies.
- A licensing deal may increase the probability of a profitable exit.
- You may gain the ability to market/develop/submit in regions of the world where the partner has capabilities and resources.
- Validation by pharma helps enable raising capital.

Important drawbacks include:

- If you succeed, the majority of the value in your asset goes to your partner.
- The product development strategy is no longer within your control.
- The timeline for development and commercialization is not within your control.
- Your partner will prioritize your asset within their broader portfolio, which may not match your objectives.
- If pharma drops your compound the repercussions are significant.

What is most striking about the traditional licensing approach is how much value most companies give away to their partners in exchange for the certainty of upfront payments and the promise of ongoing royalties. When we modeled several typical licensing scenarios, using different milestones, royalty rates, and exclusivity periods, our analysis always found the biotech innovator retaining a minority share of the total value of the asset.

Of course, in the traditional licensing model, the licensor trades the short-term certainty of upfront payments and development milestones against the risk and uncertainty of the drug development, regulatory, and commercialization process longer term. Since the majority of development projects fail, this could be viewed as a prudent course of action.

However, with the emergence of highly targeted precision medicines, companion diagnostics, biosimilars, and molecularly targeted therapies for rare diseases, one might argue that in several areas, the risks of development, regulatory, and commercialization are somewhat mitigated by advancing science, and the value proposition for the licensor needs to improve.

An Alternative Model to Capture More of the Value of Your Asset

With our broad spectrum of clinical, commercial, and consulting development capabilities, inVentiv is in a strong position to help early stage companies pursue a more flexible strategy. We can entertain significant discounts on clinical work in exchange for your commitment to conduct commercialization work with inVentiv, should your drug be approved. Specifically, we can help you:

- Complete clinical trials and conduct any post-approval trials required.
- Develop and execute risk evaluation and management strategies (REMS).
- Write key publications and take on other post-submission/approval tasks.
- Develop the pricing and market access strategy, and launch plans through our consulting business, Campbell Alliance.
- Capitalize on established payer relationships to strategically enhance product launch plans and clinical study design.
- Develop the PR and advertising strategy as your Agency of Record, with the broad range of product naming, marketing, public relations, and other strategic communications capabilities in our commercial portfolio.
- Detail the product as your sole source provider, as inVentiv Health is also one of the world's largest contract sales organizations.

Partnering with inVentiv in this alternative approach may allow you to garner a much larger share of total profits than a traditional licensing approach with upfront payments and ongoing royalties. As an example of the long-term strength of our alternative approach to partnership, we have modeled revenue projections and share of value of a hypothetical product under two scenarios:

A: Traditional Pharma Partnering Model
B: inVentiv Convergent Services Model

(See Figure 2.)

Figure 2.

Modeling Revenue Split

Traditional Pharma Partnering Model

	Innovator	Pharma Partner
COGS	0%	100%
R&D	50%	50%
Sales & Marketing	0%	100%
Royalty	12.5% of gross sales	

inVentiv Convergent Services Model

	Innovator	inVentiv Health
COGS	100%	0%
R&D	75%**	25%*
Sales & Marketing	100%**	0%
Royalty	0%	

** As discounted services* *** Includes fees to inVentiv Health*

Milestones to Innovator:

Signing:	$25 mil.
Approval:	$100 mil.
$500M sales:	$50 mil.
$1B sales:	$100 mil.
TOTAL:	**$275 mil.**

General Assumptions Applied to Both:

Inflation:	3%
Discount rate:	13% – Innovator 9% – Pharma partner or inVentiv Health
Tax rate:	15% for everyone
Model Period:	January, 2013 – January, 2033

This table illustrates some of the fundamental differences between the traditional pharma model and inVentiv's alternative approach, with general assumptions such as 3% inflation and 15% tax rate applied to both sides. In both scenarios, inVentiv data was used to estimate all costs over the life of the development and commercialization of the product.

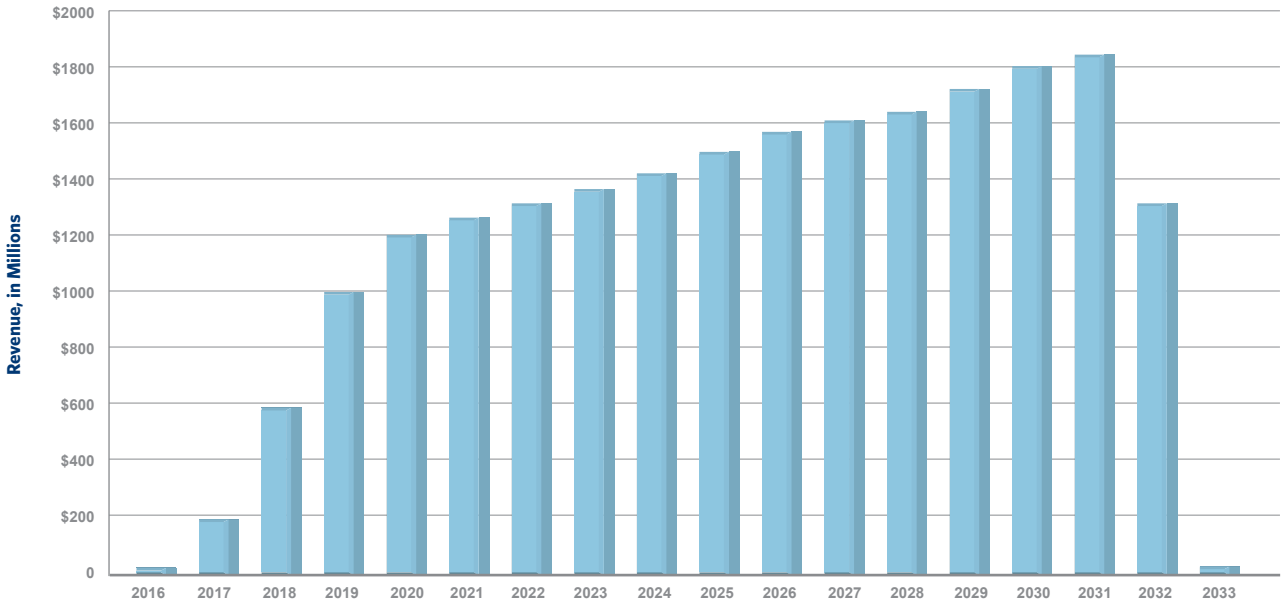
The chart below represents a revenue curve generated for our hypothetical asset. The curve is based on inVentiv data from areas of high unmet medical need such as Oncology or Autoimmune.

After three years of development expenses, our model depicts 17 years of soild growth, peaking in the year 2031 at over $1.8 billion. *(See Figure 3.)*

Figure 3.

Hypothetical Revenue Generation, 2016–2033

Based on prior experience in areas of high unmet medical need



To summarize the results:

Traditional Pharma Partnering Model

- Pharma partner assumes 100% of Costs of Goods Sold (COGS, Sales, & Marketing).
- Splits Research & Development (R&D) 50/50 between Innovator and Pharma.
- Royalty: Innovator gets 12.5% of gross sales.

inVentiv Convergent Services Model

- Innovator assumes 100% of COGS, Sales & Marketing.
- Innovator is responsible for 75% of R&D, while inVentiv's 25% share comes in the form of discounted clinical services provided.
- No royalties are received by the innovator, and none granted to inVentiv.

The most profound difference between the two approaches comes in the modeling for the retained share of risk adjusted for net present value (NPV). *(See Figure 4.)*

As you can see, under the traditional Big Pharma approach, the pharma partner keeps over 80% of the retained value, while the innovator is left with a mere 17%.

Conversely, the inVentiv model represents a near mirror image, with the vast majority of retained value staying in the hands of the innovator (84%) while inVentiv get 16%.

In addition to the obvious NPV benefits, inVentiv's alternative partnership provides a variety of benefits for early stage development companies, including:

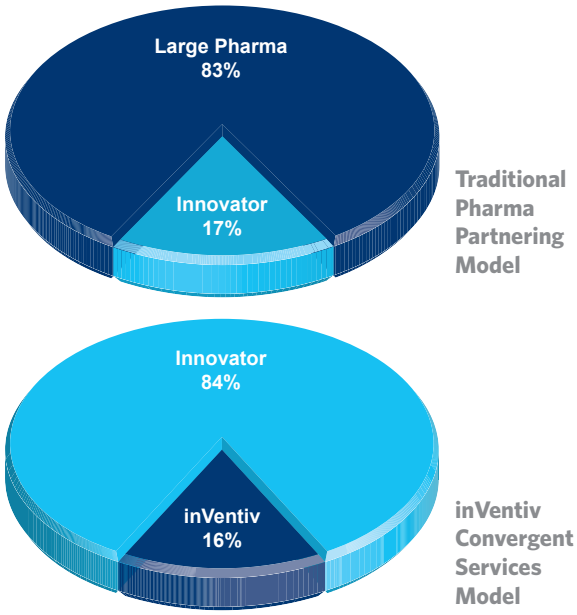
- A deal can be structured that conserves capital early on, to help optimize the valuation of your company to the initial investors. This results in a better return to the founders of the company.
- Your strategy is the one that is executed. inVentiv collaborates and applies expertise throughout the product life cycle, but all final decisions are yours.
- Together, we drive the timeline for development and commercialization. inVentiv's technical expertise and resources are devoted exclusively to your asset, not shared across a portfolio of assets.
- Your development and commercial rights are not geographically restricted. Our global capabilities ensure your company drives value globally.

Companies that succeed with this approach may extend the reach of their development dollars and may even find they are able to fund clinical programs for other molecules with significant scientific merit.

In addition to providing substantial discounts for your commitment to future commercial work, inVentiv may also consider risking some percentage of our fees based on regulatory approval of your compounds.

Figure 4.

Retained Share of Risk Adjusted NPV



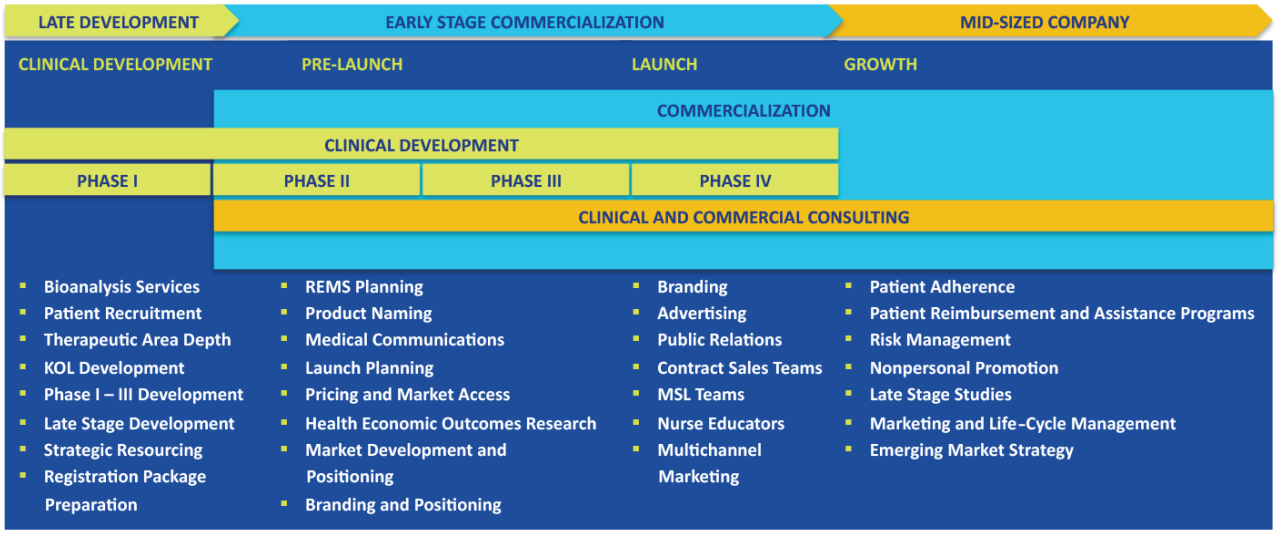
In this type of model, we provide fee discounts across our entire service portfolio. For each compound that gains regulatory approval in a major market, we receive a 3x payout on the discount provided. For compounds that do not receive approval, we absorb the discount.

Before entering such an arrangement with you, inVentiv will complete due diligence on the scientific merit of each compound, the level of unmet need, the pricing potential, and likely launch dates and revenue potential.

Once we agree to the partnership, you will enjoy access to the full breadth of our clinical, commercial, and consulting capabilities. inVentiv Health supports biotechnology and pharmaceutical companies throughout the entire product life cycle. *(See Figure 5.)*

Clinical Development — Alternative Deal Structures

Figure 5.



We are also flexible and willing to explore creative ways to become your clinical development partner.

- **Risk-Share Deals.** We can commit to a "fixed-fee" budget that reduces or eliminates the need to generate change orders. In this type of arrangement, we would need to be involved upfront and participate in study design, feasibility, and site selection. We then fix the enrollment timelines and fees to conduct the study. Assuming no changes beyond our control (e.g., regulatory), the study costs for our fees would remain fixed, with no change orders. These types of models have the added benefit of providing an implicit bonus and penalty for inVentiv. If we can beat the study timelines, we collect the same fees and our profit is higher, thus aligning our interest with yours. If we miss the study timelines, the extension of time is at our cost and our profit is reduced. Changes beyond our control might also affect study cost, in which case we would generate a change order to the study budget.

- **Penalty and Bonus Structures.** Typically, we tie a percentage of our contract to achieving key operational milestones. At the start of the study, we agree to the target completion for the milestones chosen (e.g. Last Patient In, Database Lock, or CSR filed). We then agree to an on-time period (e.g., ±30 days) in which no bonus or penalty would accrue. Anything outside that window triggers a bonus or penalty payment. Every study is different. We evaluate the appropriateness of a bonus penalty, the timelines, and the percentages or dollars we would include before the study starts. As in a fixed-fee arrangement, we will need to be involved upfront and participate in study design, feasibility, and site selection.

- **Fixed Unit Costing.** Another way inVentiv can provide a degree of budget certainty and control is to fix the cost of individual unit prices across a study region for similar studies running concurrently. Should the number of units change (either up or down), those incremental unit prices would remain fixed. There would be no change in the unit price, only in the number of units. This allows you to manage a pool of units over a group of studies.

- **Driving Broader Program Efficiencies.** As part of our commitment to delivering cost improvements and efficiencies, we can also commit to cost reductions for larger programs. Programmatic outsourcing savings can range from a 10% to 30% reduction of fees compared to smaller studies conducted on a standalone basis. The largest savings come when studies are conducted for a single compound with the same or similar indications.

About InVentiv Health

inVentiv Health has a wealth of experience conducting programs in this manner and consistently realizing efficiencies. And because we have our very own strategic resourcing division, inVentiv brings even more value-added benefit to your execution strategy, as we can effectively staff any project on very short notice.

In all our strategic relationships, we create actionable plans and manage success through a proven governance structure. Key stakeholders from your company will join inVentiv Health representatives from consulting, medical, regulatory, clinical operations, commercial operations (when necessary), and business operations (finance, business development, and executive leadership).

We often create separate committees to assess and monitor our business relationship (an executive committee) and execution strategies (steering committee). We meet regularly under a charter jointly written and agreed upon with the client. These committees track and review our work using a predetermined set of metrics to quantitatively and subjectively assess the health of our partnership.

Figure 6.

inVentiv Health holds a unique position in the pharmaceutical services market today. We have built a broad spectrum of capabilities, ranging from a best-in-class CRO to all the commercial and consulting services required to launch and fully commercialize your product.

Our privately held company earns approximately $2 billion in annual revenue and has served clients in the pharmaceutical and biotech industries since 1995.

Learn more at www.inventivhealth.com.