DHC 10 YEARS

DARK HORSE CONSULTING

AN INVESTMENT & DILIGENCE CASE STUDY SAMPLER

Accelerating cell and gene therapies through unmatched expertise

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Our Core Capabilities

- Product & Process Development
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Buyer-Side Diligence in CGT Tools & Tech

Why DHC?

- Expand Client Bandwidth
- **Provide Additional Technical Expertise**
- Solve Existing Problem (Remediate)

The Ask

Diligence in cell and gene therapy (CGT) requires not only the necessary research, but also an integrated in-depth analysis and interpretation of the findings based on a deep understanding of the technical field. This investor client required rapid and thorough diligence on a potential acquisition target (a viral vector tools and tech company) including review and assessment of the potential target's IP portfolio and the competitiveness and relative strengths of its products as compared to the competitive landscape.

Core Capabilities

DHC's Approach

Focusing on the target entity's flagship product, DHC performed a detailed, technical, and IP-driven analysis of the target entity's technology. Our team:

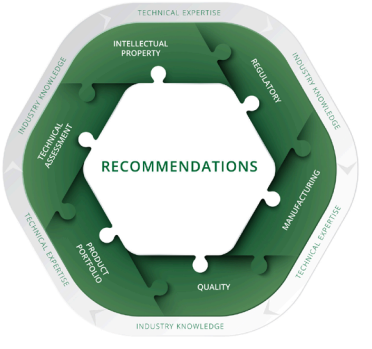
- Evaluated the target entity's patent portfolio for coverage of its commercial and soon-to-be launched products, including claim scope, geographic coverage, and remaining term. We performed a comprehensive deep dive into the IP rights (patents) across the globe, with a particular focus on jurisdictions with a high commercial value.
- Assessed the target entity's "competitive moat" by evaluating and weighting the scope of patent coverage, assessing the relative value of know-how in the field of the target's flagship product, and considering competitors' potential workarounds, technical capabilities, market presence, and market share.
- Further evaluated the flagship product's technical and commercial performance, using, for example, the following tools:
  - a blinded "voice of customer" survey, which assessed customer perception of the company and its flagship product relative to competing products
  - a critical review of performance data (provided by the target company) with a head-to-head comparison of the flagship product with competing products
- Considered intangible factors contributing to the flagship product's market adoption, including the degree of market "stickiness" and the factors in this particular industry that contribute to customer loyalty or lack thereof.

Provided an objective and unbiased assessment of the target entity's technology within a tight deadline, allowing the client to achieve a high level of confidence within a short deadline for an investment decision.

The Impact

DHC provided the client with a detailed and unbiased assessment of the target entity's technology, including evaluation of the target entity's existing and soon-to-be launched products in the marketplace vis-à-vis competitors' similar products. Our client gained a clearer understanding of the technical capabilities of the target entity and its competitors, their relative positions in the market landscape, the status of the target entity's IP assets, and an assessment of the perceived competitive advantage that the target's flagship product held in the marketplace. The deliverables provided by the DHC team armed our client with a complete slate of information necessary for effective decision-making on the potential investment.

DHC's multifaceted approach to buyer-side due diligence



The comprehensive assessment for each potential target in question includes evaluation of technical, financial, regulatory, and intellectual property consideration, enabling a holistic picture of target value.

Landscape Scan of Investment Opportunities in CGT Tools and Technology

Why DHC?

- Expand Client Bandwidth
- Provide Additional Technical Expertise
- Solve Existing Problem (Remediate)

The Ask

DHC is uniquely positioned to identify attractive investment opportunities in the CGT space through integration of our detailed understanding of CGT technologies, regulatory requirements, industry trends, and business and intellectual property considerations. In this case, an investor client requested DHC's assistance in identifying potential investment targets within the CGT Tools and Technology space that were aligned to their investment thesis.

Core Capabilities

DHC's Approach

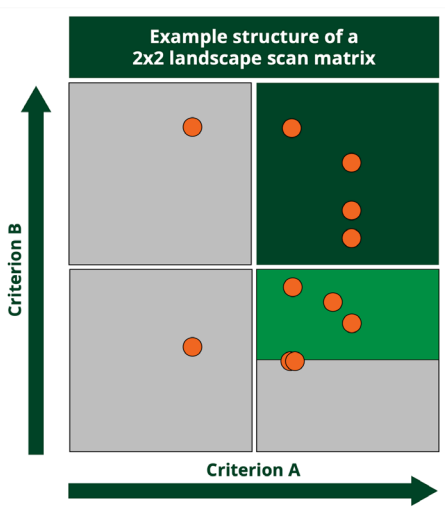
First, DHC compiled a "long list" of ~100 tools and technology companies active in the CGT space.

1. Next, the working team performed a high level scan to identify a "short list" of high priority targets based on high level financial and technical considerations using internal DHC knowledge, in addition to company websites and other publicly available information.
2. The prioritized "short list" targets were assigned to DHC Subject Matter Experts in their particular market segments for evaluation based on a predetermined, standardized scoring system designed to evaluate technical, market, and strategic considerations.
3. A subset of the "short list" targets also underwent an intellectual property (IP) review by DHC's IP Practice Expert, based on an assessment of the likely importance of IP protection for establishing their 'competitive moat.' The IP review evaluated breadth of claims, global reach, remaining patent term, and licensing status for key intellectual property protecting core assets of the target entities. The results of the IP review were integrated with other market considerations such as potential market stickiness and/or name recognition of the technology to develop an overall view of the target companies' competitive position.
4. A final assessment included a detailed review of each company, complete with quantitative scoring that ranked each target on two orthogonal criteria of importance for the investment thesis. Ultimately, a dozen potential investment targets were provided to the client, bucketed into two different investment categories.

A review of this complexity often, counter-intuitively, eventually boils down to an unexpected clarity of choice.

The Impact

The client received a summary presentation outlining key data for all "short list" targets, as well as a quantitative ranking of each target on a 2x2 matrix. This provided the client with a dozen potential candidates for consideration, as well as a quantitative assessment of the pros and cons of each entity. In addition to the summary presentation, detailed back-up information was provided in the form of a spreadsheet database of company information and brief IP summary memos on each entity for which an IP analysis was performed.



Due Diligence of Phase III Readiness for Cell Therapy

Why DHC?

- Expand Client Bandwidth
- Provide Additional Technical Expertise
- Solve Existing Problem (Remediate)

The Ask

CMC is frequently on the critical path for cell and gene therapy product development timelines. A venture capital firm requested a rapid evaluation of CMC Phase III readiness for a cell therapy asset in which they were considering investing.

Core Capabilities

DHC's Approach

In this case, the review of the asset had eight components. The review took into consideration Phase III readiness as well as next steps that would be necessary for suitability for BLA (Biologics License Application). Over the course of a fast-tracked three week review, DHC performed:

1. A process-trending and reproducibility analysis of the company's manufacturing process based on historical records of previous batches in Phase 1 and Phase 2.
2. A raw material suitability analysis, considering the materials' fitness for both late stage and commercial manufacturing.
3. A review of the facility's QMS (quality management system), in addition to projecting forward to identify future gaps in commercial readiness.

   In many cases, Quality Systems support is not a stand-alone project, but instead an element that appears to varying degrees throughout another project. In the case of this example, we see a QMS-readiness review making an appearance: both conceptually, and as part of a follow-up on-site audit (#3 above & #7 below).
4. An analysis of the facility's qualification status and validation master plan.
5. A review of the development status of critical in-process and release assays used to characterize the product.
6. A review of all recent FDA correspondence with a particular eye to any potential issues that could impact Phase III initiation and/ or BLA approval.
7. An on-site quality and technical audit to determine Phase III readiness and PAI (pre-approval inspection) readiness of both the manufacturing facility and quality management systems.
8. The writing/delivery of a final report summarizing all identified risks to Phase III readiness. Within the report, each element was given a risk rating (critical – significant – moderate – minor) which takes into account anticipated time and a rough cost estimate for remediation if necessary. Recommended timing and approach for remediation were provided for each item. Additional recommendations were provided regarding next steps for items with little risk for Phase III readiness, but that would require remediation prior to BLA.

The Impact

Within three weeks of start, the client had in hand a report enabling them to make an informed investment decision and providing a post-investment roadmap to Phase III and commercial CMC readiness.

Due Diligence for Cell Therapy Company Formation

Why DHC?

- Expand Client Bandwidth
- **Provide Additional Technical Expertise**
- Solve Existing Problem (Remediate)

The Ask

A prospective investor client approached DHC with a fast-turnaround request for an assessment of a business proposition: merging two cutting-edge CGT technologies to spin out a new cell therapy company. One asset had promising early clinical safety and efficacy signals for its early clinical stage cell therapy products. The second target asset had a state-of-the-art technology to enable a next-generation approach to those products. The ultimate goal was to combine these two technology platforms to be able to build out new therapeutic pipeline products. DHC needed to consider both of these assets from the perspective of CMC, nonclinical and business risk, evaluate terms of manufacturing agreements, and consider the scientific rationale for merging these two platform technologies. Additionally, DHC advised the client on the intended budgets, hiring plans, timelines, and milestones for the new entity.

Core Capabilities

DHC's Approach

As with most due diligence projects, the timeline of this request was accelerated to align with the predetermined deadline for either agreeing to the deal or walking away.

A key element of the request was to evaluate business risk: specifically, the overall cost projections for continued future development of each asset. The client had prepared a draft financial business plan that DHC was to review to ensure alignment with industry standards. A first step was to consider whether the costing proposal was sensible: did the numbers represent realistic cost expectations?

DHC performed a deep dive review of data rooms supplied by both target assets, allowing for a detailed look at the CMC and nonclinical current state and future development plans. This review included nonclinical data packages that had been previously generated in addition to budget, timelines, and past regulatory correspondence (for both US and non-US health authorities). DHC summarized the merits of the investment, identified potential development risks, and aligned on appropriate strategies and proposed partnership opportunities.

On-site diligence included DHC travel to current sites for both assets, as well as to the intended manufacturing partner for the new company. This enabled a technical and quality review of all facilities and ongoing operations in addition to an in-depth business strategy discussion with leadership for both target assets. Leadership for all parties involved attended this onsite quality and technical review, which allowed for strategy partnership and business discussions between investors and both target assets with DHC present. This offered a high degree of transparency for all parties.

This client ask evolved over time, with DHC eventually becoming responsible also for evaluating and providing input on the documents for the agreement itself. Although Dark Horse Consulting does not provide legal advice, we reviewed and evaluated the master service agreements and key elements of the deal from a quality, technical, and business perspective in partnership with the client's legal advisors.

In the final stages of the discussion, DHC met daily with the client and their lawyers to assist in finalizing documents to broker the deal, ensuring that they could meet their deadline.

The Impact

The client considered both assets sufficiently de-risked to warrant finalizing the purchase, especially considering the adjustments DHC recommended making to the deal.

Dark Horse also provided the client with sufficient confidence regarding assurances of what quality, CMC, and regulatory needs the program would likely require and how long they were expected to take. Another outcome of this diligence experience was that the investor now has a better understanding of what will go into completion of a successful licensure, providing more control over the future of the asset.

A Roadmap to IND

Why DHC?

- Expand Client Bandwidth
- **Provide Additional Technical Expertise**
- Solve Existing Problem (Remediate)

The Ask

For a roadmap to IND the most commonly asked questions are: how much time will it take us to get to IND, how much will it cost, and what are the key milestones? These requests typically arise from early preclinical stage programs just beginning their transition from discovery to formal product development. Often clients will have demonstrated *in vitro* proof-of-concept and completed one or more pilot animal studies. The client may also have high level CMC development and nonclinical study plans for which they are seeking DHC review and input. In other cases, clients come to DHC during mid- to late-stage preclinical development, wanting to ensure that their nonclinical IND-enabling study plan is appropriately aligned with CMC activities. Having a clear and well thought out, integrated cross-functional project plan that includes timelines, costs and value inflection milestones is also a critical success factor for fundraising.

Core Capabilities

DHC's Approach

An effective roadmap to IND considers both efficacy and safety through the lens of the client's business strategy and risk tolerance. It addresses timeline and budget, including an in-depth expectation of what the client's future capital needs will be over time. Typically, a deliverable will include a Gantt chart to provide side-by side tracking of various nonclinical, clinical, regulatory and CMC activities to ensure that these are synched up appropriately in a way that will translate into an achievable timeline. Tying costs into this chart is also necessary for identifying where in the process the client might need a cash infusion.

Capturing regulatory interactions is critical: when should a pre-IND meeting be planned in the schedule? Would the product be appropriate for and benefit from an INTERACT meeting or from another early engagement forum such as CBER Advanced Technologies Team (CATT)? The roadmap will include where those interactions make sense in terms of the overall project architecture and what data sets should be viewed as 'must haves' versus 'nice to haves' to enable a successful regulatory engagement.

DHC consultants build an understanding of the intended clinical use of the product and the proposed efficacy models and then collaborate and consult with the client to understand the overall development trajectory as well as key driving factors such as what the study needs are in order to determine a starting clinical dose. Depending upon the complexity of the model and the dose administration procedure, DHC will discuss and advise on appropriate study plans to support the intended use. DHC can provide advice on guiding delivery methodology: whether an off-the-shelf option is available or if a custom device is needed (and if so, what the development path for that device may look like).

Some clients already have draft nonclinical study designs to consider and some need assistance in putting them together. DHC consultants take into account suitable study size, what the endpoints are, how many studies are needed, how to determine dose-ranging, selecting a suitable CRO, and so on.

Upon client request, DHC consultants offer a draft study plan complete with current pricing information from one or more CDMOs/CROs. Vetting and selection recommendations for choosing a manufacturing partner may be another DHC project.

Sometimes the IND roadmap is supported by a hiring plan, should the company be in growth mode. DHC's industry experience allows for a keen eye on what expertise will be needed at what point of time and how and when to allocate a full-time employee in-house vs. when to contract out support.

On occasion DHC receives an accompanying request to build a pitch deck for a round of fundraising. Investor interest can be dependent on receiving the details laid out in a roadmap, because knowing each step of the process not only increases investor confidence but helps to define use of proceeds and identify the critical value inflection points that will enable each future round of fundraising.

The Impact

A DHC-provided roadmap to IND ensures a robust review and deep technical (and industry-specific) understanding of a program's current standing, with a clear set of recommendations of next steps. Some clients begin pursuing those next steps immediately, while others use the roadmap to enter a fundraising round first. A detailed roadmap demonstrates to investors a cohesive plan for use of proceeds, including activities, costs, timelines, and inflection points.

Voice of Customer Survey for Cell Therapy Raw Material

Why DHC?

- Expand Client Bandwidth
- Provide Additional Technical Expertise
- Solve Existing Problem (Remediate)

The Ask

This client had identified an opportunity for offering higher quality raw materials for cell therapy manufacturing and was interested in gathering information about the current and future market expectations to both pressure-test and guide the business opportunity.

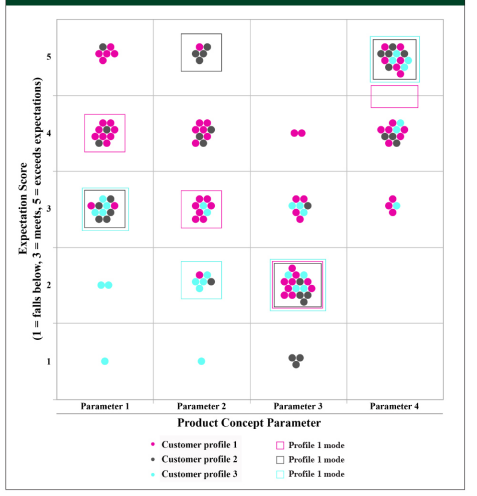
Core Capabilities

DHC's Approach

DHC and the client jointly determined that a Voice of Customer survey of cell therapy developers would best address the parameters that should be taken into account when considering the raw material needs of the potential market. These parameters included the projected demand for the raw materials, manufacturing and testing requirements, variations in the product offering that would appeal to distinct market subsegments, and what kind of characterization data might interest a future customer. The steps taken to complete the project were as follows:

1. DHC evaluated capabilities and expertise of the client to develop a full picture of what the client would eventually be prepared to offer.
2. The client and Dark Horse worked together to craft an appropriate interview guide (set of survey questions) to address current and projected future needs for the raw materials, as well as the criteria to be considered. DHC's diverse experience in cell therapy manufacturing processes and innately deep understanding of these processes provided an unmatched depth and accuracy to these questions.
3. DHC reached out to our extended network of cell therapy experts and potential future consumers of the new product offering. Note the symbiotic nature of this experience: DHC's contacts are an extremely accurate targeted subset of potential clients, meaning not only is the market research on point, but the beginnings of a manufacturer/client relationship is being seeded during the market research process.
4. Dark Horse compiled the survey and completed the first stage of the process: an online survey to capture the quantitative elements in question.
5. That survey was followed by detailed customized in-person interviews to allow gathering of further, highly targeted information. Dark Horse's market researchers are scientists speaking to scientists. This shared language and understanding of the CGT space enhances confidence and is simply more enjoyable and fruitful for all parties concerned.
6. DHC compiled information from the online surveys and interviews, including statistical analyses run on the quantitative answers. (See sample dot plot.)
7. Client received a written report and presentation summary overview of all information obtained, in addition to strategic recommendations and a detailed list of key factors to consider.

Customer Ratings of Product Concept Parameters by Expectation Score



Survey participants were asked to rate four different parameters of the proposed product concept using an Expectation Scale of 1-5 (1 = falls below expectations, 5 = exceeds expectations). Survey participants were divided into three customer subgroups corresponding to distinct subsegments of the product's target market (denoted by color). The mode for each product parameter rating by customer subgroup is indicated by a box outline and corresponding subgroup color.

The Impact

The client's vision and next steps came into alignment, with a thorough understanding of the opportunity available in light of the needs and expectations of the target customer.

Market Research for a Cell Therapy Technology

Why DHC?

- Expand Client Bandwidth
- Provide Additional Technical Expertise
- Solve Existing Problem (Remediate)

The Ask

Entering the Cell & Gene Therapy space is an attractive proposition for many companies with diverse product portfolios. Successful entry into such a complicated space, though, requires thorough market research and/or modeling. In this case a full Market Research review, including a Voice of Customer survey, would lead to a forecast revenue model for effective planning.

Core Capabilities

DHC's Approach

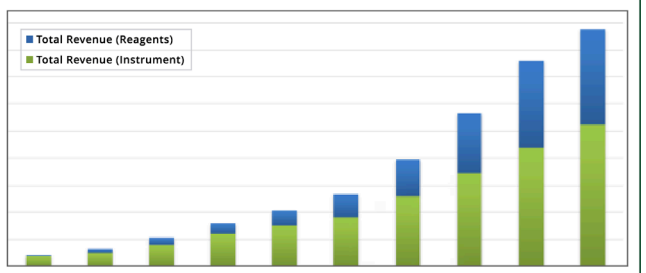
Before releasing a supporting technology into the cell therapy field, this client retained Dark Horse for a full market research workup, including:

- A Voice of Customer survey (*learn more about such surveys on the facing page, page 8*).
- A portfolio expansion project. Evaluating other technologies in the cell therapy field provided the client with a sense of what they might choose to add to their portfolio. The first step is to consider a landscape scan (*a detailed example of a different landscape scan project appears on page 4*) to identify the other players in the field and their current and future offerings. This provides a list of possible competitors, collaborators, and/or potential M&A opportunities.
- A go-to-market strategy for launching their product commercially. This includes guidance on maximizing relevant selling features and identifying best-fit marketing forums (conferences, webinars, publications, etc) as well as proof-of-concept data packages for each recommended forum.
- Identifying a target customer profile: companies that are most likely to consider adopting the product, likely decision-makers, and profiles of those who will be using the technology. This process includes a consideration of selling points and related messaging points.
- A revenue forecast model, including assumptions arrived at through the exercises above.

The Impact

Dark Horse provided this client with a one-stop shop for market research, due diligence on expansion opportunities...and a guiding vision of the science and technical questions necessary to create an accurate to-market strategy. Unlike a traditional market research firm, Dark Horse brings centuries of expertise in the CGT field to bear when considering the competitive landscape, competitive advantages, and target customer profiles.

Revenue Forecast for Technology Platform X



Having market research completed by a company with extensive technical experience in the market in question is what distinguishes Dark Horse from other possible sources for market research.

CGT Manufacturing "Hotel" Facility

Why DHC?

- Expand Client Bandwidth
- Provide Additional Technical Expertise
- Solve Existing Problem (Remediate)

The Ask

A U.S.-based company planning to develop and build a multi-tenant "hotel"-style facility for early-stage CGT manufacturing required strategic guidance. This included a review of the facility conceptual design with voice of customer interviews, facility demand modeling, and the development of market insights, all to inform the client's planning and decision-making process.

Core Capabilities

DHC's Approach

Engaging Dark Horse at an early stage of business case development provided the greatest opportunities to influence the strategic direction of a project. In this project, the client planned a new GMP facility providing leasable suite space to multiple tenants, with DHC providing recommendations for key issues such as:

- Operating cost and pricing models
- Facility design and suite layout to maximize flexibility to accommodate multiple CGT modalities
- Regulatory considerations for multi-tenant occupancy of a "hotel"-style GMP operation
- Facility demand forecasting and targeting of potential tenants including region-specific analysis
- Benefits of a hotel facility over conventional build-or-buy manufacturing scenarios
- Positioning of a hotel service offering and competitive landscape analysis

Within each suite, the DHC team defined the CGT modalities, scales, and equipment types that would be best suited to the proposed clean room layouts. The DHC team also developed details of tenant services that should be provided by the facility landlord and recommendations for how to ensure flexibility for the diverse range of customers needing to be accommodated.

Revenue modeling and pricing benchmarks for tenant services were also provided to the client for use in building out their detailed financial models. Demand modeling was provided to forecast 10-year growth in the need for CGT manufacturing space, broken down by modality.

Finally, DHC made initial recommendations for positioning the client's proposed "hotel" facility within the spectrum of currently available service offerings, illustrating the competitive landscape with case study examples.

Throughout this project, DHC ensured that a broad team of consultants provided their expertise to cover facility design, business strategy, regulatory compliance, and market analysis skill sets.

The Impact

DHC's facility design review provided a valuable set of recommendations that were used by the client's architect to improve and refine operability, flexibility, and compliance of the facility. This included a careful focus on shared areas of the building and controls needed to segregate tenant operations and manage GMP flows of people and materials. DHC's work allowed the client to refine their planned hotel facility service offering with a focused set of facility user requirements, target customers, market positioning, and critical revenue/cost data.

Pegasi: COGs and Facility Planning

Why DHC?

- Expand Client Bandwidth
- Provide Additional Technical Expertise
- Solve Existing Problem (Remediate)

The Ask

An international tools and technology company requested a market analysis of the gene-editing and advanced therapies space as well as a facility buildout plan to manufacture a critical component for gene therapy applications.

Core Capabilities

DHC's Approach

Providing realistic future expectations for the client required an understanding of the many elements at play. DHCs internal experts provided assistance in identifying components that would be involved in the client's strategy and how they would interact with one another, from market size to facility requirements to regulatory and beyond.

This request also made use of DHC's proprietary data-modeling platform, known as Pegasi. This platform is flexible, applying customized input to quantitatively describe a range of probable outcomes for a variety of client queries. In this case study, DHC's Quantitative Modeling team focused on use of the market analyses, COGs assessment, and resource modules of the Pegasi platform.

The client had not previously produced this critical manufacturing component, but they did have experience with a related product and had a clear vision of what percentage of the market they would need to capture and within what time frame in order to meet their related revenue projections.

This clarity allowed DHC to work backwards from the market expectations to arrive at expectations for process and facility necessary to produce the requisite amount of raw material.

The first step in this exercise was to estimate the market demand. Dark Horse conducted a landscape scan in addition to voice of customer surveys to get a clear picture of the current market need and also consider the growth of the market over time. Once the market demand forecast was quantified and target ranges for market penetration over time were applied, the Dark Horse team then had a clear view of the production demand the client could expect for the critical component.

With the demand known, the DHC team identified and quantified the process equipment and infrastructure systems necessary to meet the production demands, then produced a sample facility map outlining production suites and supporting space. Included in this facility map were expected schedules for the multi-phase facility buildout, with the facility expansion aligned to the estimated market growth and market penetration.

The DHC team considered how a manufacturing effort of this size would reside within the client's current infrastructure, complete with a review of the full complement of labor (how many individuals with which skill sets would be necessary to begin and continue work on a site of this size) down to hazardous materials usage and waste disposal. After modeling the demand, infrastructure, and labor, DHC was able to analyze not only the COGs and anticipated revenue but also the sensitivity of the profit ranges in response to changes in any variable fluctuation.

Due to the evolving nature of the regulatory framework for cell and gene industry in general, and this manufacturing component in particular, it was critical to include a regulatory assessment to complete this exercise. DHC regulatory experts identified regulations currently in place in various markets, provided best practices recommendations, and weighed in on the direction regulatory guidelines may go in the future.

The Impact

Pegasi's results were presented to the client and considered within the clients' portfolio and company mission. First to consider the final materials was the relevant team in charge of implementation, to ensure an internal alignment of expectations across the responsible project managers and the corresponding in-house technical experts. The results also went to senior management to ensure that they had clarity on all decision points necessary to efficiently take the next steps in adding this opportunity to their range of business offerings.

DHC-investor projects in the public domain

While the majority of DHC's clients prefer to keep our relationships confidential, occasionally a client chooses to publicly disclose our working relationship. Of the 70+ projects we've done to date with investor clients, three clients have publicly acknowledged Dark Horse Consulting as advisors, making it possible for us to reference them below.

early 2021:

Charles River Laboratories (CRL) acquired Cognate BioServices, allowing CRL to expand scientific capabilities into the emerging, high-growth cell and gene therapy CDMO sector and establish a comprehensive solution from discovery and non-clinical development through CGMP manufacturing in advanced drug modalities. DHC acted as CRL's strategic advisor in the transaction.

early 2022:

Global Healthcare Opportunities (GHO Capital Partners LLP) invested in RoslinCT in order to significantly increase RoslinCT's development and manufacturing capacity and support customer acquisition and product diversification, while benefiting from GHO's sector expertise and international resources to accelerate growth. This allowed the business to build on its best-in-class therapies to better service a growing international client base. DHC acted as GHO's technical advisor in the transaction.

late summer of 2022:

Approximately 8 months after the aforementioned RoslinCT investment, GHO made a majority investment in Lykan Biosciences, facilitating the merger between RoslinCT and Lykan. The combined entity offers process development expertise and cGMP manufacturing for autologous and allogeneic cell therapies via a more complete global footprint, greater scope of services and general operational capabilities, and an increase in capacity. DHC acted as GHO's technical advisor in the transaction.

fall of 2023:

Lauxera Capital Partners invested in Swedish regenerative medicine leader BioLamina AB to support further expansion of its global footprint, widening of its product offerings, and scaling of its production capacity at multiple quality levels to meet the strong demand from both innovative biopharma players and from life science tools and services companies. DHC was a part of an advisory team supporting Lauxera in its commercial, manufacturing, and regulatory due diligence.