Emerging Companies & Investors

Life Sciences & Health Care

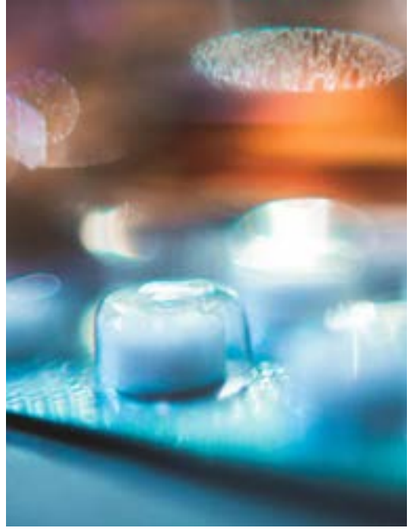
Hogan Lovells

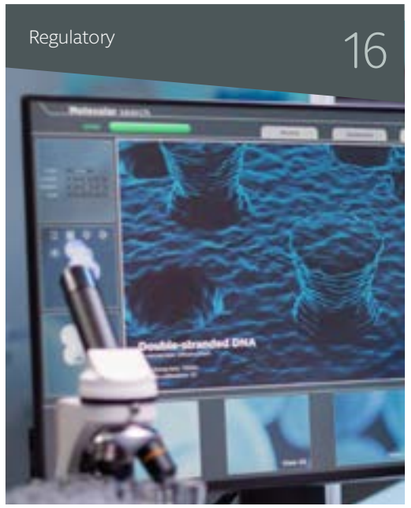
We don't just get you off the ground, **we're here to grow with you.**

As an emerging company or investor, you face no shortage of new legal and business challenges, typically on a very condensed timeline. When the stakes are this high, working with the right strategic advisors who understand the business implications of the legal and regulatory landscape will prime you for success. Finding the right partner who has a shared passion for your mission and the sense of urgency to meet the objectives you wish to achieve is key.

That's where we come in.

Your business, intellectual property (IP), and regulatory and reimbursement strategies don't operate in a silo and neither do we. As one of the world's leading life sciences firms working with an array of innovators, our integrated team provides unparalleled insight into how your business and IP strategies intersect with regulatory and reimbursement considerations and how that translates to the financial markets. We offer the rare ability to tackle all your business-critical issues no matter what the issues are or where they arise.





Going global.

Health is global. Your company can be too. We help emerging companies and their investors expand into international markets, ensuring your products reach those who need it most.

Navigating regulatory hurdles.

Regulatory pitfalls can make or break a life sciences company. As the world's preeminent regulatory practice, we don't just handle due diligence. We help companies navigate the best possible pathways to regulatory approval and stay compliant once your product hits the market.

We've done this before.

Our team of more than 500 life sciences and health care lawyers worldwide advise more than 2,000 companies in the industry, from early stage inventors and entrepreneurs through Fortune 500 life sciences companies. Our collective knowledge, experience, and network enables us to put you in the best possible position for success.

We've got you covered

From corporate formation to patent protection and strategy to initial financing rounds, we help your company lay a strong foundation, with life sciences and health care industry expertise at the forefront throughout. As your business grows and your needs evolve, so does our team of lawyers who can support your company's strategic business needs relative to your product's development stage, including regulatory approval planning, clinical trial design, pricing and reimbursement strategy, licensing, collaborations and other commercial transactions, and commercialization and product launch planning. And when the time comes, we're prepared to support you in exit planning and execution through IPO, mergers and acquisitions, or asset monetization through strategic collaborations and cross-border licensing.

Corporate

- Corporate Formation and Governance
- Executive Compensation, Employment Benefits, and Share Incentives
- Financing
- Licensing and Commercial Transactions
- Mergers and Acquisitions
- Tax

Intellectual Property

- Portfolio Planning, Analysis, and Development
- Patent Prosecution
- Patent Landscape and Patentability Analysis
- Validity and Infringement Opinions
- IP Due Diligence and Valuation
- Trademarks
- Trade Secrets

Regulatory

- Clinical Trials
- Regulatory Approval Planning
- Pricing and Reimbursement
- Commercialization and Product Launch
- Data Privacy and Cybersecurity
- Due Diligence

Corporate

Our knowledge of the venture capital market and extensive experience in representing strategic corporate investors, venture capital funds, and emerging companies enables us to offer our clients sophisticated advice, resources, and capabilities in a broad range of jurisdictions.

Building on decades of experience, our global team of venture capital lawyers provides multidisciplinary counsel to venture capital funds and emerging companies in connection with fundraising, investments, corporate governance, and exits. Our team also represents strategic corporate investors on a broad range of transactions, including investments made in connection with simultaneously negotiated commercial transactions, in contemplation of a later joint venture or merger and acquisition transaction, or on a long-term stand-alone basis.

We deliver a full range of legal services around the globe tailored to meet the needs of businesses as they grow. Our team represents investors and emerging companies in seed and later-stage investments, and we leverage the firm's breadth and depth of capabilities to assist with our clients' evolving legal needs.

We strive to build strategic and valuable connections among investors, entrepreneurs, and companies, and our involvement in a wide range of transactions helps give us insight into the prevailing terms, structures, and practices in connection with investments in companies at all stages of development.

Guiding companies through every stage of growth.

Mature

- Corporate governance and board advising
- Securities law reporting and compliance
- PIPEs/ Follow-on and registered direct offerings
- Dispute resolution and litigation
- Mergers and acquisitions
- Licensing and commercial transactions

Growth

- Venture capital financing
- Private equity financings and mergers and acquisitions
- Licensing and commercial transactions
- Restructurings and recapitalizations
- Initial public offerings/ SPAC de-mergers
- Secondary sales

Emerging

- Corporate formation and entrepreneurial services
- IP strategy and protection
- Seed, SAFE, note, and angel financing
- Equity plan creation and administration

Spotlight on: Licensing and Commercial Transactions

Delivering efficient and practical advice that gets the job done. For emerging companies, Hogan Lovells offers unparalleled insights based on our considerable experience working with a variety of life sciences clients - from emerging biotechnology and digital health companies launching their first product to the largest global life sciences companies looking to fill their product pipeline. We understand and work together with you to solve the toughest legal issues around the world. We help you identify and mitigate risk and make the most of opportunities.

Our teams are highly experienced in structuring and negotiating all kinds of transactions in the life sciences and health care industry, from licensing arrangements, research and development collaborations, clinical and commercial collaborations, manufacturing and supply agreements, to marketing and distribution agreements and other strategic arrangements require to research, develop and commercialize therapies and technologies.

We understand the challenges and opportunities that strategic alliances and other partnering relationships present, whether from the view of the emerging company or potential development and commercialization partners, and we work with you to structure the transactions that help you achieve your business goals while mitigating legal risks.

Our diversity of experience, deep industry knowledge, and understanding of the interplay of economic, governance, regulatory, and intellectual property issues give us a unique perspective on complex contracts and strategic arrangements. We work seamlessly across our global network and with our colleagues to provide unparalleled transactional support and advise within this highly regulated industry.

Representative experience:

AlloVir, a clinical stage T cell company, in connection with its collaborations with Baylor College of Medicine, manufacturing agreements, clinical trial site negotiations, and other matters.*

OptiNose on its IPO, and public follow-ons, Series D financing and prior rounds.

RTW Investments on multiple equity investments, including Monte Rosa Therapeutics and Umoja Biopharma.

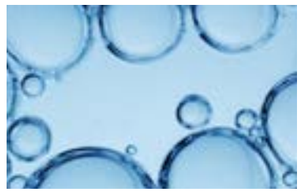
GEXVal on its Material Transfer Agreement and non-binding term sheet in relation to its product GXV-002, a development candidate (a small molecule) for the treatment of rare or intractable disease in the pulmonary and cardiovascular disease area.

Aimmune Therapeutics on the drafting and negotiating of specialty pharmacy, specialty distribution, third-party logistics, hub services and other related outsourcing agreements in preparation for initial launch of its immunotherapy treatment for peanut allergies.

Cancer Focus Fund, an oncology-focused venture capital fund partnered with MD Anderson Cancer Center, in connection with its formation and approval by the University of Texas System.*

Plus Therapeutics, a clinical stage cancer company, in connection with its technology licensing, debt restructuring, financing transactions, sponsored research, and other legal matters.*

MedinCell on a joint venture agreement and an exclusive manufacturing contract for supply of polymers.

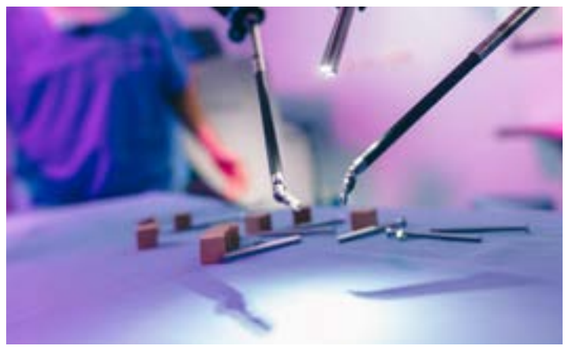


New Enterprise Associates on multiple equity investments, including in Tiburios, Centrixion, Miurm, Allokos, NightStarX and Vtesse

Tesaro on its exclusive outlicense with Takeda for the commercialization and clinical development of Niraparib in Japan.

AavantiBio on its US$107M Series A financing.

Sensors for Medicine and Science on its US$54.1m Series D financing.



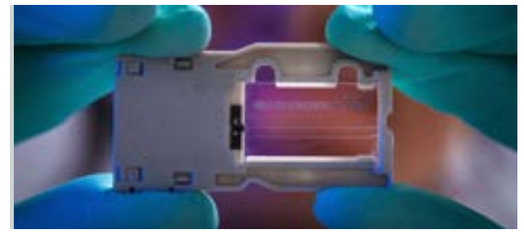
Morphosys on a worldwide collaboration and license agreement with Incyte Corporation to co-commercialize tafasitamab for the treatment of B cell malignancies.

Kite Pharma, on its investment in HifiBio's US$67m Series C financing.

OncoResponse on its preferred stock financings of over US$100m, strategic collaboration with MD Anderson Cancer Center, and other legal matters.*

Kite Pharma on exclusive collaboration with Sangamo Therapeutics to use Sangamo's zinc finger nuclease technology for the development of next generation ex vivo cell therapies in oncology.

Centogene on its €25m Series A financing.



Gilead on its multiple equity investments including in Vaccitech, ViraCyte, Tango, Vineti and Allovir.

Pacira Pharmaceuticals on its agreement with DePuy Synthes to jointly market and promote the use of EXPAREL™ for orthopedic procedures in the U.S.

Novartis Institutes for Biomedical Research on its investments in Blade Therapeutics' Series B financing and Ideaya Biosciences' Series A financing.

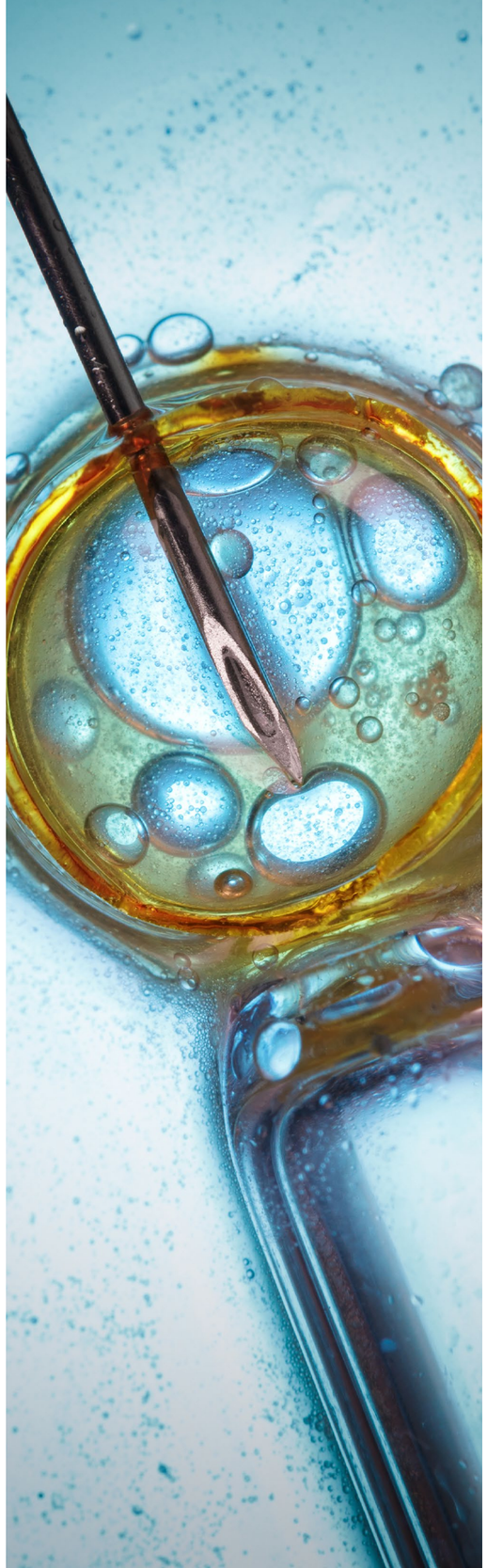
SymBio Pharma on its exclusive in-license with Chimerix for brincidofovir for all human indications excluding smallpox virus.

Fred Hutchinson Cancer Research Center in its investment in Juno Therapeutics' US$134m Series B financing and US$176m Series A financing

*Matters handled prior to joining Hogan Lovells

Intellectual Property

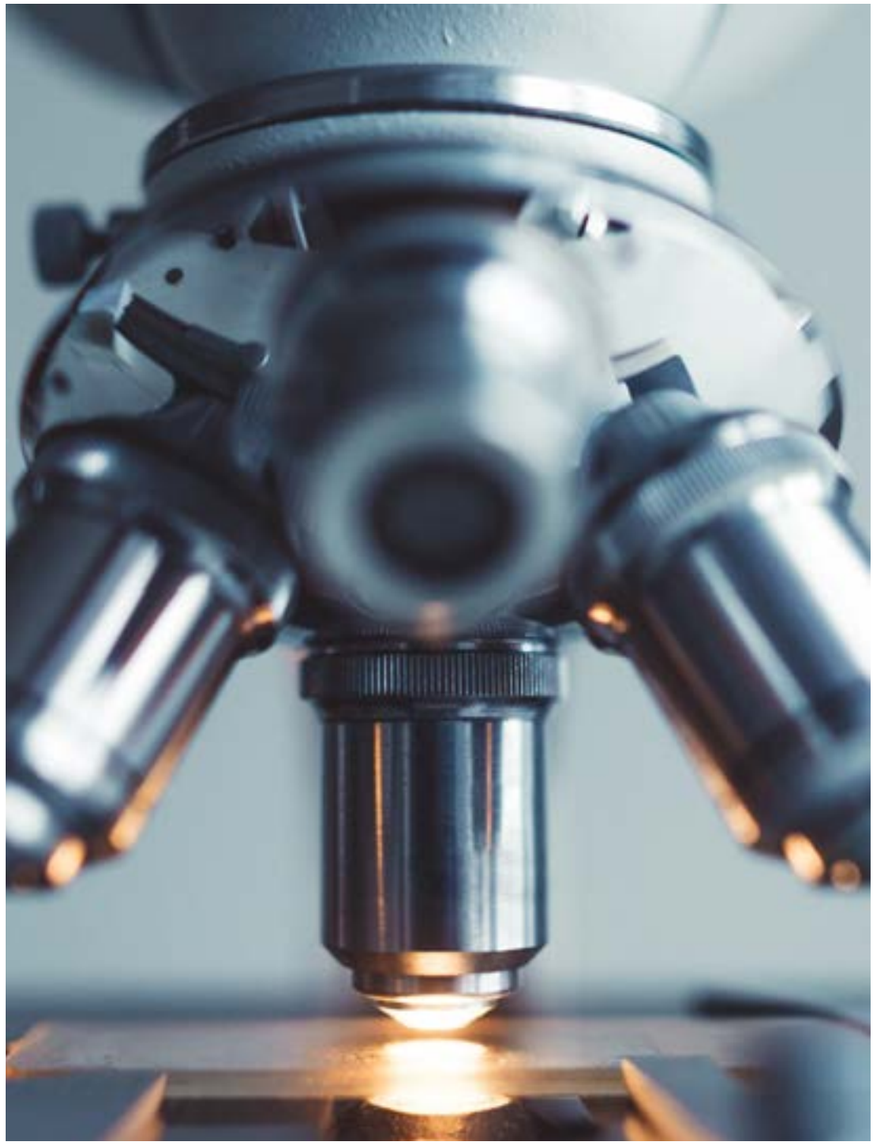
With a team of IP professionals, we are with you from initial idea to global roll out. We provide tailored advice on the full range of legal considerations critical to life sciences and health care companies including IP strategic counseling, portfolio development, due diligence, commercial agreements, and licensing. As a global full service IP firm we advise clients on the spectrum of IP including patents, trade secrets, trademarks, and copyrights.



We help our clients leverage their IP to obtain new funding, identify new clients strategic partners, acquire a new company, and pursue business expansion. Our integrated business view means we not only aim to protect a product or technology that will be developed and enforced in litigation, but also enable clients to use IP as a business development tool to attract funding and advance other business objectives.

Our advice is commercially relevant and technically sound. Many on our team hold advanced degrees, including Ph.Ds. in fields such as chemistry, biology, physics, computer science, immunology, and biotechnology. We provide strategic advice to a range of innovators across the digital health, biotechnology, medical device, consumer product, and health care sectors.

Representative experience:

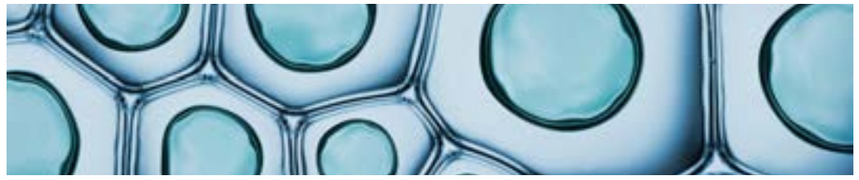


Werewolf Therapeutics on IP strategy and patent prosecution.

Abcuro on patent prosecution and IP strategy.

Elucida Oncology on IP counseling and patent prosecution matters.

Applied Therapeutics on managing its patent portfolio, IP counseling and strategy, and IP due diligence.



Pyxis Oncology on IP strategy, patent prosecution, and supporting IP diligence for its $168 million IPO and $152 million Series B financing.

Tessera Therapeutics on its IP needs including patent prosecution, strategy, and transactional matters.

Institute for Molecular and Clinical Ophthalmology Basel on IP transactional matters and patent prosecution.

Freya Biosciences on developing IP strategy and patent drafting.

Pulmatrix on patent prosecution and IP counseling for their iSPERSE dry powder technology.

Opus Bio on patent prosecution and strategy for its lentiviral gene therapy products.

Genome Medical on patent prosecution, prior art searches, and patent strategy development.

Regulatory

Accomplishing business goals in such a highly regulated industry requires practical, integrated legal analysis and advice. With a global regulatory team of over 150 lawyers, we provide specialized advice to companies through their entire journey – from concept ideas and process development to seeking regulatory approval and managing product life cycles.

Hogan Lovells offers the largest life sciences and health care regulatory practice across the world, with recognized leaders in Washington, Brussels, Munich, Paris, and Amsterdam.

Throughout the product development process, there are multiple steps and regulatory requirements that need to be closely managed to set you up for a successful outcome. Our team assists with developing practical strategies for product design and negotiate the necessary agreements to enable you to quickly and smoothly initiate your clinical trials around the world. This includes negotiating clinical trial agreements, license agreements, and clinical research collaboration agreements with government bodies, industry partners, and academic institutions.

When it comes to health care and reimbursement strategy, we help you structure research budgets and interact with physicians and health care providers so that you can be confident in your compliance with U.S. Medicare fraud and abuse laws, equivalent rules in EU Member States, international anti-corruption laws, and other applicable legal requirements. In addition, our product liability practice provides practical advice in structuring clinical trials and drafting labeling to avoid liability, including from clinical trial injury claims and litigation.

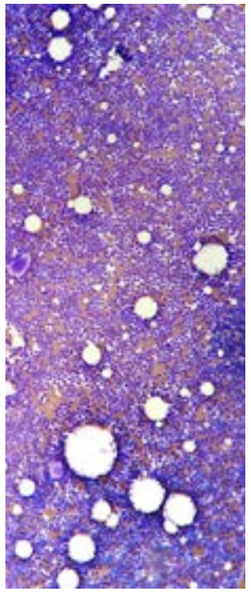
As part of the regulatory pathway it is important to understand the potential and actual risks when considering entering into a transaction. Our team works closely with you to detect, manage, and mitigate any risks related with your business. We perform due diligence investigations of regulatory and reimbursement issues and risk factors.

With a cross-disciplinary approach, a deep talent bench, and our knowledge of and contacts within U.S., European Union, and Asian government agencies, we ensure a comprehensive, integrated and risk-based strategy for issues that arise in drug and device development. We are here to help you achieve your long-term business objectives.

Representative experience:

Numerous health services companies and health plans on numerous breaches involving tens of millions of records, including advising on forensic investigation, breach notification, and communications and interactions with consumers and customers. We also handle the investigations by federal and state health and insurance regulators, state attorneys general, and law enforcement.

A range of life sciences companies on data privacy and security matters, including advising on international data protection, CCPA, data use agreements, and privacy policies and procedures, as well as performing comprehensive website reviews.



Multiple small companies on their participation in U.S. government funding programs (grants, cooperative agreements, contracts) for medical research and public health projects.

Leading digital health companies on data privacy matters with regard to clinical trials in the EU involving both pan-European strategic advice and detailed country-specific guidance.

Emerging biotech companies on data questions related to structuring clinical trials, informed consents, patient support programs, and specialty pharmacy arrangements.

Medical device start up on due diligence to uncover several important FDA issues that substantially altered the investors valuation.

Medical device start up in obtaining clearance of a 510(k) notice without clinical data for a cardiac bypass device after the FDA required PMA approval.

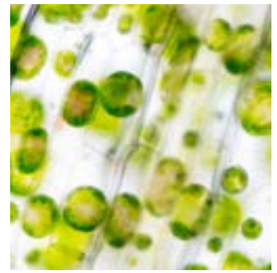
Heartflow in obtaining Medicare coverage and reimbursement for its new software technology.

Novartis on the development of its digital health strategy.

European biotechnology company on its product designation as a biologic rather than a new drug, a more advantageous designation considering future would-be competitors.

Spark Therapeutics on a wide range of regulatory, reimbursement, commercial, and compliance issues in connection with the clinical development and product launch of the innovative prescription gene therapy Luxturna®™.

Juno Therapeutics on its comprehensive FDA regulatory, reimbursement, and launch planning for its CAR-T therapies under development.



Multiple clients in the CAR-T space on manufacturing clinical trial and quality agreements, and regulatory and launch planning.

MyHomeDoc on its regulatory strategy, development, testing, and FDA submissions related to obtaining clearance for this remote telehealth platform. The platform allows for measurements typically done in a doctor's office to be performed at home and facilitates transfer of that information to the physician.

Case study

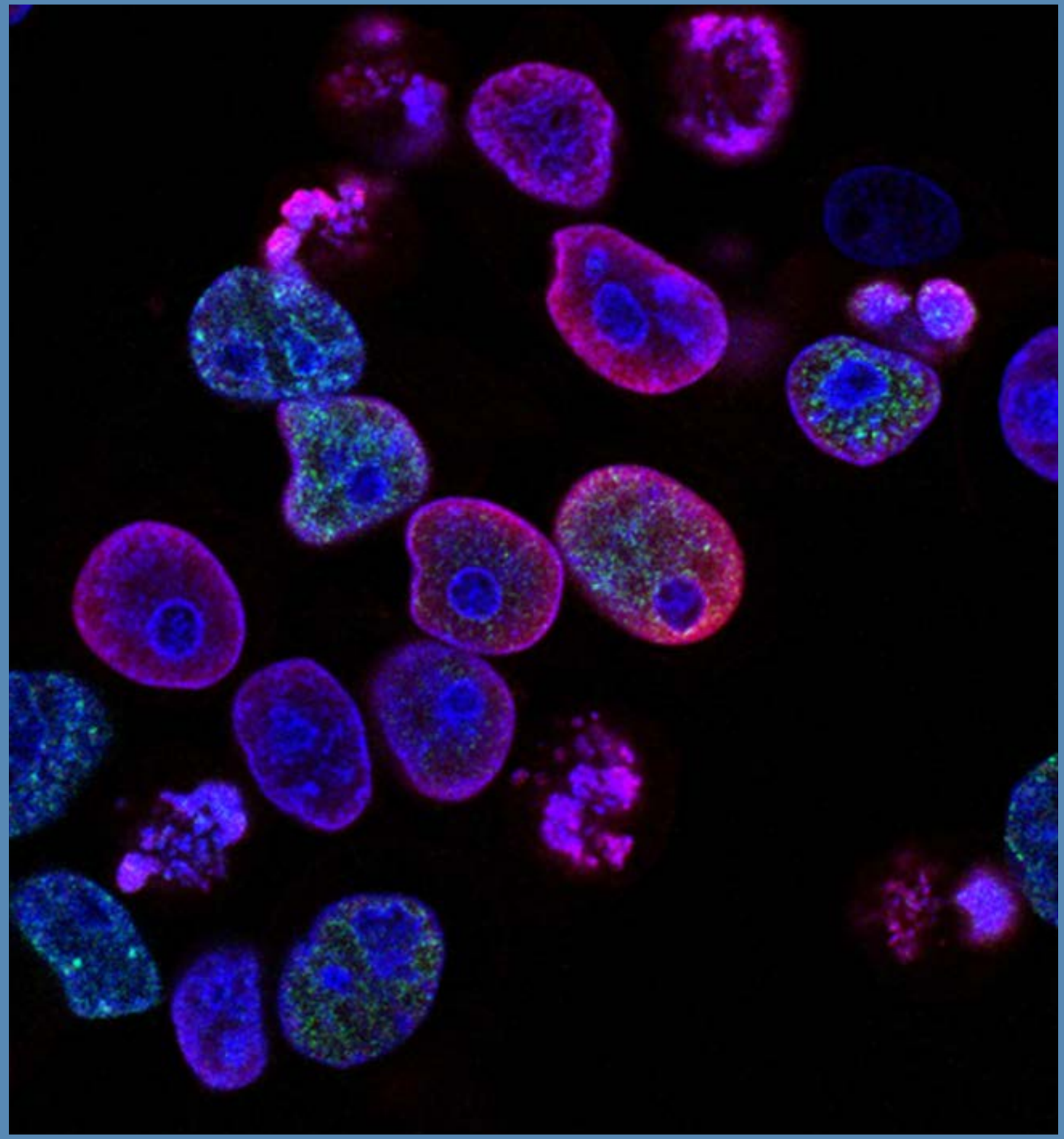
bluebird**bio**

Our global team has been assisting Boston-based bluebird bio since 2015, when they were developing a unique pipeline of gene therapy product candidates. We assisted and continue to support the company with the launch of their first gene therapy product in the EU by providing advice on regulatory matters, corporate structure, tax, employment, trade and privacy issues in multiple member states. As bluebird looks to launch in the U.S. and other markets, our global team continues to work with them, advising on commercialization of products and contract distribution, pricing and reimbursement and regulatory support around clinical trial issues for its earlier stage product candidates. Our global network of life sciences lawyers uniquely positions us to help companies like bluebird grow and launch products around the world.

Case study

Novocure

A non-invasive medical device that uses electric fields to cause cancer cells to explode with essentially no side effects or damage to non-target tissue? Sounds like a blockbuster idea. This is the idea Novocure approached our global regulatory team with 20 years ago, based upon research by its founder Yoram Palti, MD, PhD, a Professor at the Technion — Israel Institute of Technology. At the time, Novocure was just a small start-up with a handful of employees. Our Medical Devices & Technology team helped guide the company in choosing the first indication for the technology, recurrent brain cancer (glioblastoma multiforme (GBM)), through their clinical trials, through a premarket approval (PMA) application to the U.S. FDA, an Advisory Panel meeting, and ultimately to FDA approval in 2011. Following their approval, in 2015, the privately-held company which had operated using significant venture funding throughout this process, underwent an $165M IPO. Since that time, we have worked with the company on numerous additional applications for their technology, helping secure approvals for newly diagnosed GBM and mesothelioma, and assisting with clinical trials for other applications (ovarian cancer, pancreatic cancer, etc.). Throughout its lifetime, Novocure has relied on Hogan Lovells' regulatory expertise to make that blockbuster idea a reality, and to go from a small start up to a listed company with a $15B market cap and over 1,000 employees with operations in the U.S., Europe and Asia.



Let's Connect

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life-sciences

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“They are **fresh thinking** and provide a balance between policy and business decisions.”

– Client, Healthcare, Chambers USA, 2020

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