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ASIA LIFE SCIENCES SERIES

Investing in Life Sciences Start Ups in the US – Key Issues and Considerations

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Presentation Outline

1. Overview of Venture Capital Investments in the US
2. Special Issues for Investing in Private US Life Science Companies
3. Special Issues for Non-US Investors

Overview of US Venture Capital Investments

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Target Companies for U.S. Venture Captial Investments

Challenges

- Development stage businesses
- Frequently cash flow negative
- Often no revenue
- Limited sources of capital - traditional debt capital from banks not available
- Private companies - liquidity of investment limited

Target Companies for U.S. Venture Capital Investments - continued

Opportunities

- High growth potential
- Innovations in business and technology
- New markets
- Intellectual property critical to value proposition and business plans
- Investors increasingly global

Structure of Venture Capital Investments – Common Characteristics

- Target company is a Delaware corporations, taxed as a C corporation under US tax code
- Investors hold less than 50% of the capital stock and voting rights (minority, non-controlling investments)
- Investment instrument is convertible preferred stock
  - Converts into common stock
  - Different series (Series A, Series B, Series C, etc.)
  - Preferred stock has negotiated rights, preferences and privileges

Structure of Investments – Common Characteristics

- Rights, Preferences and Privileges of Preferred Stock fall into three broad categories:

1. Economic Rights
2. Governance Rights
3. Information Rights

Structure of Investments – Common Characteristics - continued

1. Economic Rights

- Liquidation preferences (priority returns in event of sale of business, liquidation or dissolution)
- Dividend
- Redemption
- Anti-dilution rights
- Preemptive rights for new issuances by the Company
- Rights of first refusal and co-sale rights on other stockholders transfer of stock
- Registration rights for the stock, if and when the company goes public

Structure of Investments – Common Characteristics - continued

2. Governance Rights

- Investor representative on board of directors/Observation rights with respect to board of directors
- Special stockholder voting rights on extraordinary corporate events (e.g., sale of business, new financings, changes of investors rights)
  - Allows investors to block such events
  - Called "Protective Provisions"
- Special voting rights of the member of the Board of Directors appointed by investor holding preferred stock

Structure of Investments – Common Characteristics - continued

3. Information Rights

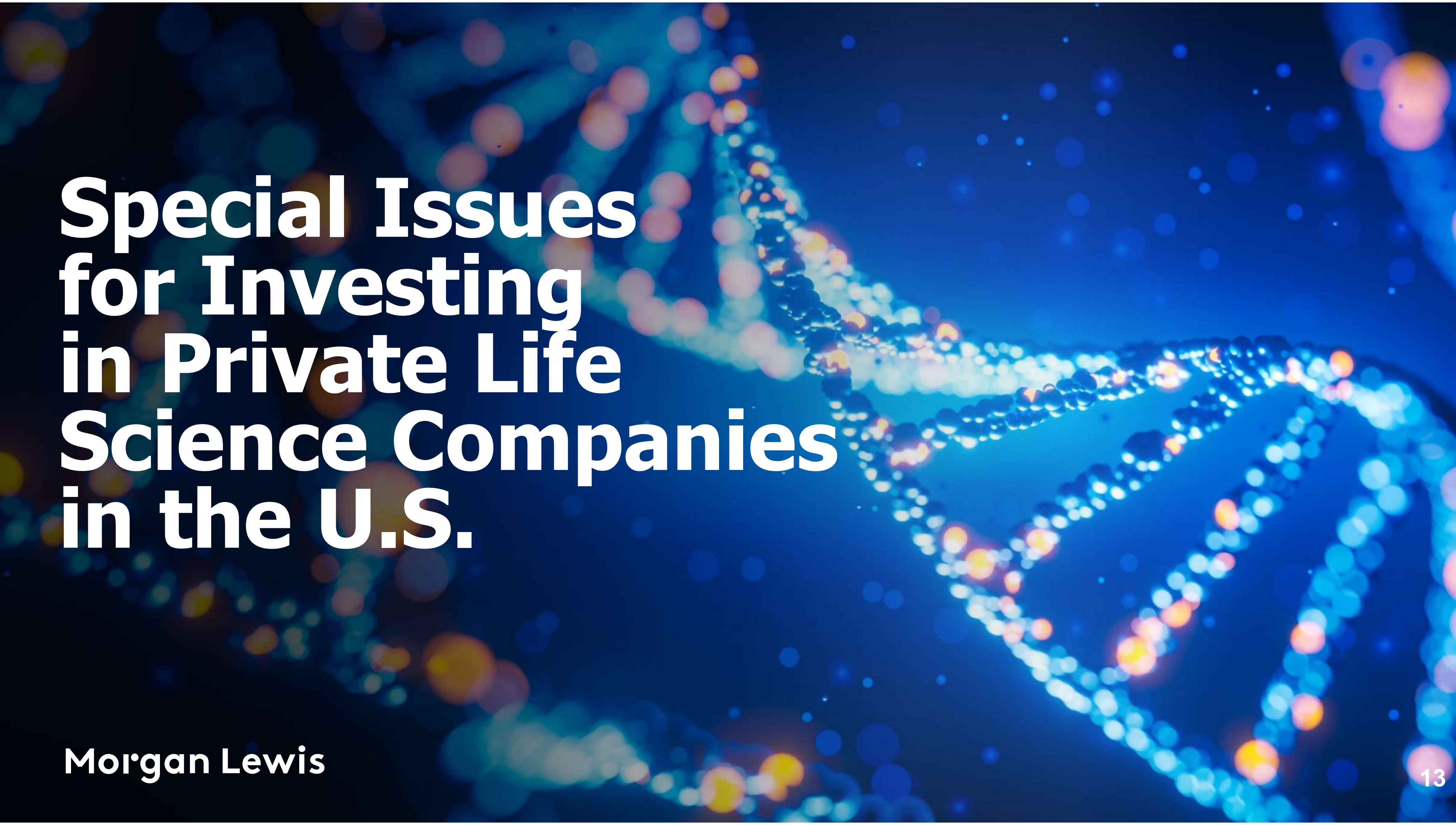
- Financial information
  - Audited financial statements – annual
  - Unaudited financial statements – monthly and quarterly
  - Operating budgets, revenue projections, monthly costs/expenses
- Business information
  - Business plan, annual operating plan, R&D plan, product roadmap
  - FDA approvals and timeline
- Meetings with management and key personnel

Structure of Investments – Common Characteristics - continued

Process:

- Business and financial due diligence
  - Precedes negotiation and signing of term sheet
- Term sheet
  - Investors' legal counsel involved
- Legal due diligence
  - Starts after term sheet is signed
  - Concurrent with negotiation of definitive financing agreements
- Definitive financing agreements
  - Typical period of time from signing term sheet to closing financing is 4–6 weeks
  - Simultaneous signing and closing

Special Issues for Investing in Private Life Science Companies in the U.S.



Intellectual Property

- Intellectual property critical to investment success
  - Right to use the technology or product to build the business
  - Ability to keep competitors from using your technology or manufacturing competing products
  - Life Science businesses are built around patent portfolios
- Due diligence often revolves around intellectual property due diligence
  - Review of owned/registered patents
  - Freedom to operate (FTO) to evaluate risk of infringement on third party's patents
- Patent portfolios
  - Claim by claim analysis
  - Each claim in the patent determines the scope of rights
  - Both quality & quantity of claims matter
  - U.S. applications vs. foreign applications

Intellectual Property (Especially Patents)

- Owned vs. Licensed IP
- Owned
  - Assignment documents properly prepared, signed and recorded?
  - Any rights of employees, consultants and service providers?

    See Employment Agreements, Invention Assignment Agreements, employment policies
- Licensed
  - Exclusive vs. non-exclusive
  - Field of use
  - Territorial coverage
  - Right to enforce (generally for exclusive licensee)
  - Right to direct and control patent prosecution
  - Right to sublicense

Regulatory Framework

- Life Sciences is a heavily regulated industry
  - Successfully navigating regulations and associated development steps is critical to success of business
- Key Areas of Regulation
  - Safety and efficacy
  - Pricing and Reimbursement
  - Research

Regulatory Framework - continued

Key regulatory agencies

- US Department of Health and Human Services
  - US Food & Drug Administration (FDA)
    - safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, and cosmetics
  - Centers for Medicare & Medicaid Services
    - oversight of the Medicare program, the federal portion of the Medicaid program and State Children's Health Insurance Program, the Health Insurance Marketplace
  - National Institutes of Health
    - supports biomedical and behavioral research with the United States and abroad, conducts research in its own laboratories
- State agencies for healthcare and consumer protection

Partnerships and Collaborations

- Partnerships and collaborations are a unique attributes of life science industry
  - Partnerships and collaborations among life science companies' are integral part of success
  - Used to address unique obstacles in the life science industry
    - Share development costs
    - Leverage resources of large pharmaceutical companies for research and development, clinical studies, distribution channels and marketing
    - Allow companies to diversity product portfolios and hedge risks
    - Avoid or reduce need to build marketing and distribution capabilities
  - Create different economic models
- Types of partnerships
  - Joint development
  - Manufacturing and branding
  - Distribution, sales and marketing

Other Sources of Capital

- Non-dilutive sources of capital
  - Significant reliance on early-stage funding from governments and other non-investor sources (foundations, etc.)
  - If used, must understand associated limitations (e.g., government march in rights for intellectual property)
- Sponsorships by academic institutions and government grants come with strings attached
  - Reporting obligations
  - March-in rights (see above)
  - Joint ownership of IP
  - Other government regulations, e.g., Federal Acquisition Regulations (FAR), which regulates how federal executive agencies purchase and acquire supplies and services with appropriated funds

Day to Day Oversight of Portfolio Company

- US venture investors maintain close contact with private companies in portfolio
  - Combination of board attendance
  - Visits to physical location of companies
  - Frequent communication with executive management
- Special challenges for investors in Asia
  - Maintaining close contact is challenging due to time zones and geographic distance
  - Need for local presence or investment personnel
  - Language and cultural differences
  - "Deemed exports" in export controls regulations may prevent investors from access to certain information
  - Other restrictions due to CFIUS

Special Issues for Non-US Investors: CFIUS and Foreign Direct Investment Regulations

Committee on Foreign Investment in the United States (CFIUS)

- **CFIUS is a U.S. government interagency committee that reviews foreign acquisitions of U.S. businesses, as well as minority investments in U.S. businesses and other transactions in the interest of protecting U.S. national security**
- **The members of CFIUS include the following U.S. government agencies:**
  - Department of the Treasury (chair)
  - Department of Justice
  - Department of Homeland Security
  - Department of Commerce
  - Department of Defense
  - Department of State
  - Department of Energy
  - Office of the U.S. Trade Representative
  - Office of Science & Technology Policy

Committee on Foreign Investment in the United States (CFIUS)

Why does CFIUS matter for foreign investors participating in venture capital financings of U.S. life science companies?

- Participation by the foreign investor may cause the transaction to fall within the jurisdiction of CFIUS, and if so, the transaction could be blocked or significantly delayed if CFIUS believes that your transaction raises U.S. national security concerns
- Non-controlling investments by a foreign investor may also implicate CFIUS if the U.S. company is engaged in a business involving "critical technology" that raises concerns from a U.S. national security perspective
- In certain cases, CFIUS can even unwind a transaction after it has closed
- If forced to divest, very difficult to sell shares to third parties, and most likely must take a loss on investment
- Future opportunities to invest in U.S. life sciences companies may be curtailed
- Reputational risks

CFIUS and FIRRMA

- The Foreign Risk Review Modernization Act of 2018 (FIRRMA) is the latest comprehensive amendment to national security reviews and is embedded in the Defense Production Act (DPA), a statute that includes a range of broad national security authorities.
- The jurisdiction of the Committee on Foreign Investment in the United States (CFIUS) was previously based on ownership and control (both affirmative and negative), which is defined by CFIUS more broadly to include material influence, access to confidential technical information and less-than-majority control (i.e. minority investments)
- FIRRMA expanded CFIUS jurisdiction to also include certain non-controlling but non-passive investments, as well as certain real estate investments.
- FIRRMA also made filings mandatory for certain transactions, in a departure from the previous system in which all notices were voluntary.

New Focus on U.S. Technology, Infrastructure and Data Businesses

- Key focus of FIRRMA and the implementing regulations is on investment by foreign persons in so-called "Technology, Infrastructure and Data (TID)" businesses.
- It is important for companies to determine if they have "critical technology," "critical infrastructure" or "sensitive personal data" for CFIUS purposes.
- "Critical technology" analysis heavily dependent on export controls compliance
  - Export control classifications of products (ECCN or export control classification number)
  - Startups may not have classifications
  - Investors to classify or obtain CCATS from Bureau of industry and Security (BIS) of the U.S. Department of Commerce
- There are separate regulations covering foreign investment in "covered real estate," which includes certain investments in real property within defined geographical proximity to listed ports and military installations.

Committee on Foreign Investment in the United States (CFIUS) and Minority Investments

- **After FIRRMA in 2018, CFIUS jurisdiction was expanded in scope to include minority investments and other transactions**
  - In addition to CFIUS's traditional jurisdiction over M&A deals where non-U.S. persons obtain control of a U.S. business, in 2018 the CFIUS statute was amended to add **certain non-control and/or non-passive investments involving critical technology, critical infrastructure, and sensitive personal data**.
  - Minority investments that give the foreign investor **access to material nonpublic technical information**, seat on the **Board of Directors** or observer rights on the Board, or **approval or veto rights** over key management decisions.
- **Mandatory vs. Voluntary CFIUS Filings**
  - The 2018 amendments added mandatory filing requirements for certain transactions involving critical technology and involving foreign persons with a substantial foreign government interest.
  - Even where there is not a mandatory filing requirement, a voluntary filing may be advisable because CFIUS can challenge transactions after the closing (called a "safe harbor").

Committee on Foreign Investment in the United States (CFIUS) Filings – JVNs and Declarations

- **Potential CFIUS outcomes (for full Joint Voluntary Notices)**
  - **Clear without mitigation** - transaction receives safe harbor from further CFIUS action
  - **Clear with mitigation** - transaction receives safe harbor, but enters into a mitigation agreement as a condition of CFIUS clearance. Based on the latest CFIUS data, in 2021 mitigation was required in approximately 11% of all cases filed.
  - **Presidential prohibition/divestment** - prohibitions and forced divestiture are very rare, and have generally involved acquisitions by Chinese buyers.
- **Declarations process**
  - The 2018 FIRRMA reforms also implemented a new process for filing a short-form Declaration, instead of a full Joint Voluntary Notice ("JVN")
  - Shorter review period (30 days, versus 90 days for a JVN)
  - Potential outcomes: 1) clear (with safe harbor); 2) conclude with no action; 3) request full filing; 4) require full filing

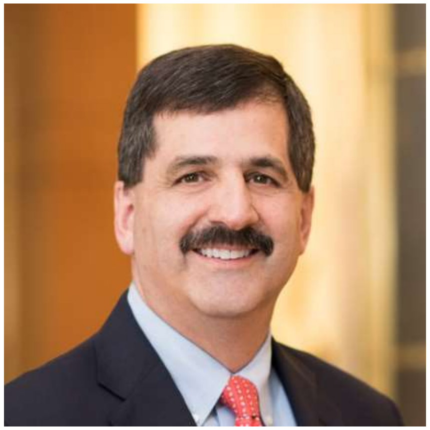
Committee on Foreign Investment in the United States (CFIUS) - Timing

- **Timing for JVNs**
  - 90-day statutory period (45-day review; and potential 45-day investigation)
  - Up to 10 days for CFIUS to accept filing and start the clock
  - Option to submit a draft filing for input by CFIUS, which typically adds at least another 10 days
  - Withdraw and refile mechanism (restarts the clock)
  - 15-day extension in exigent circumstances (rare)
  - 15-day presidential review period (for prohibition/divestment recommendations by CFIUS)
- **Compliance**
  - Mitigation agreements involve a permanent monitoring relationship with CFIUS
  - Financial and other costs to business
  - Increasing complexity of mitigation, especially in cases involving sensitive technology (including biotech and pharma) and personal data

Non-Notified Transactions

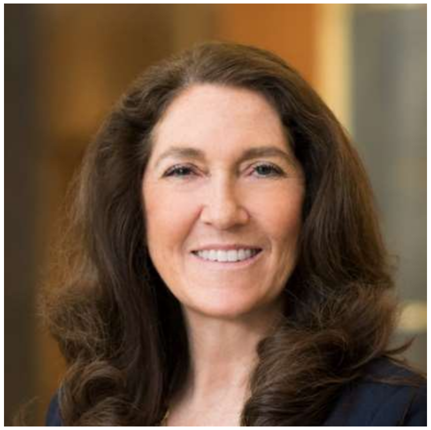
- CFIUS has increased its resources to monitor so-called "non-notified covered transactions," and since 2016 the number of reviews of non-notified covered transactions has increased, particularly involving sensitive personal data or in certain industries (e.g., Chinese investment in life sciences or semiconductors).
- It is expected that CFIUS will further increase its review of non-notified covered transactions. CFIUS also has increased enforcement action for failure to file.
- CFIUS is actively reviewing **non-notified, non-controlling venture capital investments** by Chinese investors and investors from certain other countries of concern.
- In 2021, CFIUS made a non-notified outreach in 135 cases, but required only 8 of these to submit a full joint voluntary notice.
- Even if CFIUS pulls in a non-notified transaction for a full review, that does not necessarily mean CFIUS will require mitigation or divestiture.

Morgan Lewis CFIUS Practice Group



Ken Nunnenkamp

Leader of CFIUS Working Group



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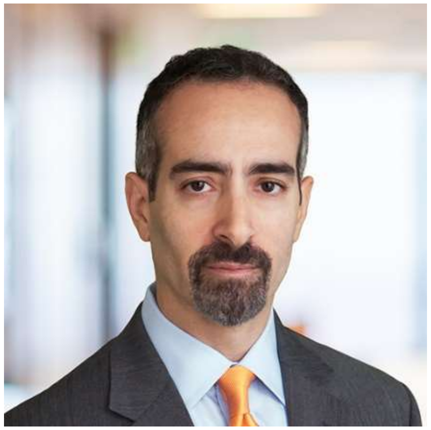

David Plotinsky


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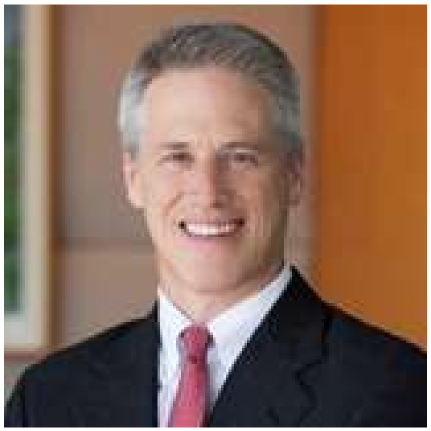
Nancy Yamaguchi advises global technology companies on cross-border mergers and acquisitions (M&A), strategic and venture capital investments, joint ventures, strategic alliances, technology transactions, and licensing. With more than 20 years of experience, Nancy is a trusted advisor to private and public multinational companies, especially those based in the United States and Japan, on all aspects of their corporate legal needs, including inbound and outbound M&A transactions.

Nancy is ranked Band 1 for Corporate/M&A: Deals in Asia by Chambers and recognized by clients as having “a business mind and tremendous attention to detail." Clients commend her for being “excellent and speaking fluent Japanese but also able to translate the cultural context and is amazing when dealing with the Japanese government.” In addition, they note that “she is great at negotiation and everything legal and is extremely helpful in concluding multinational deals."

Biography



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Scott D. Karchmer counsels entrepreneurs and emerging and established companies in business transactions. Representing global clients in the biotechnology, medical device, software, data analytics, financial services, fintech, and networking and storage industries, he advises companies at critical junctures in their lifecycles. Scott handles formation, raising funds from venture capitalists, initial public offerings, mergers and acquisitions (M&A), investments, divestitures, and other issues organizations confront. He also advises venture capital firms and other investors in connection with investments in private companies.

Counseling public companies on securities law, governance, and general corporate matters, Scott represents clients in capital markets transactions. He advises on private investments in public equity (PIPEs), registered direct offerings, convertible debt offerings, 144A offerings, and underwritten offerings. Scott is the pro bono chair of Morgan Lewis's San Francisco office. He serves on the board of directors for Legal Services for Children, a San Francisco-based nonprofit organization that provides legal counsel to individuals under 18.

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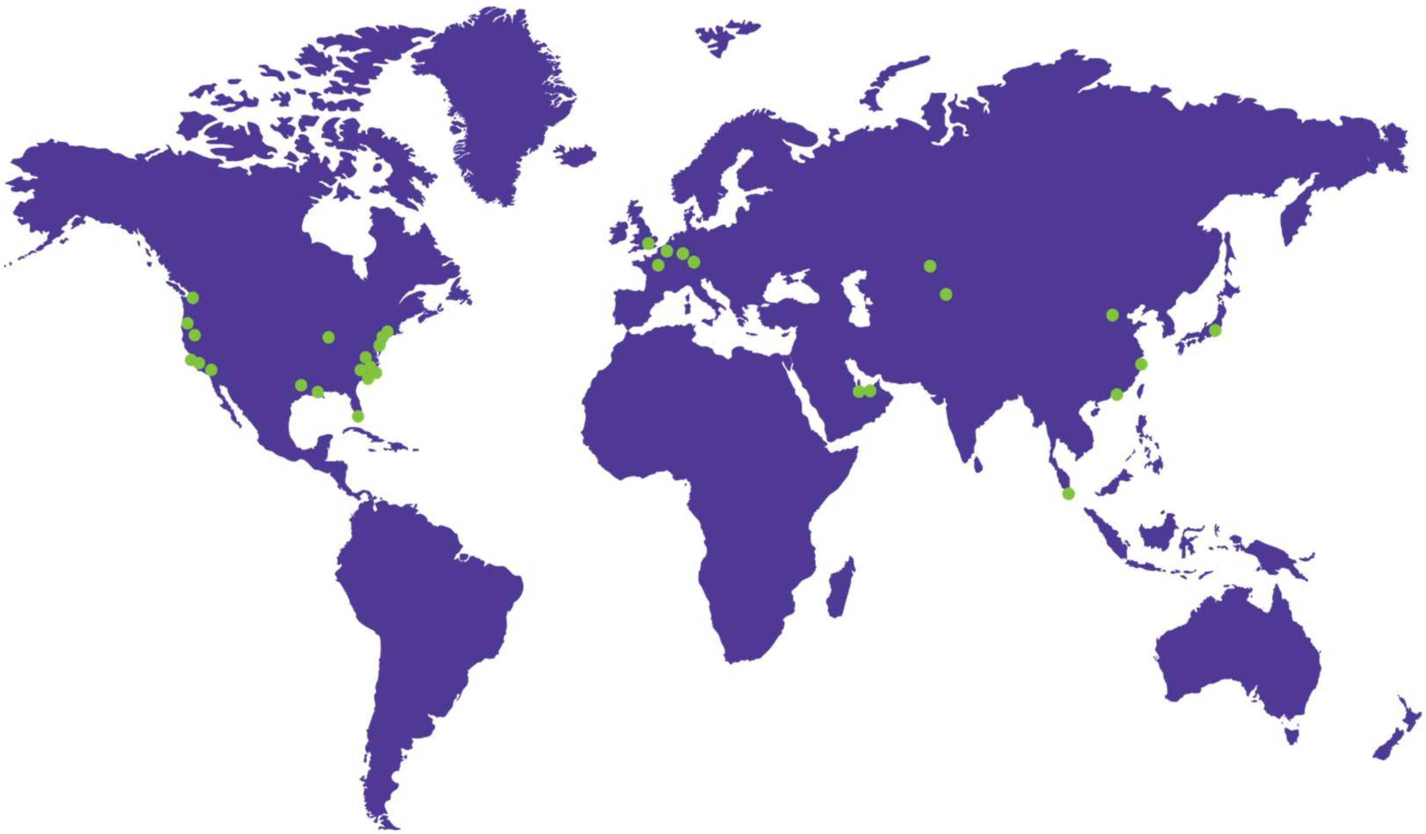

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