WINNING STRATEGIES:

How to Create, Grow, and Sustain a Successful Life Sciences Company

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WINNING STRATEGIES: How to Create, Grow, and Sustain a Successful Life Sciences Company

Beyond the Nuts & Bolts: Protecting Your IP Assets in Today's Expanding Global Market

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Panelists

Moderator:

Antoinette F. Konski, Partner, *Foley & Lardner LLP*

Speakers:

Elin Hartrum, Director, Intellectual Property,
Gilead Sciences, Inc.

Carol Cherkis, Ph.D., Life Sciences Consultant,
NewCap Partners, Inc.

Govind Gupta, Principal, Valuation & Business Modeling,
Ernst & Young

Case Study

- Case Study
- Elin is the Director of IP at NewPharma Co., a specialty pharmaceutical company that develops therapies for the treatment of neurological disorders. The company has two drugs in the FDA pipeline. The first is a small molecule to treat symptoms of early onset Alzheimer's Disease and is presently in Phase II testing. The molecule was developed by the cofounders when they were professors at State U. The technology, patents and know how are exclusively licensed to NewPharma Co. Patents were filed on the compound in the United States, Canada and Europe only. Absent any patent term extension, the patents will expire in 2022.

Case Study (Cont.)

A prodrug was developed by the cofounders after they resigned from the university and a provisional patent application was filed, followed by a PCT. The deadline to enter national stage of patent examination is due shortly and Elin is pondering the countries to pursue patent protection. The prodrugs were conceived by the cofounders in the United States but reduced to practice by a Chinese contract manufacturer following the direction and supervision of the cofounders. The prodrug is currently in Phase I of the approval process.

Elin's management needs capital to complete the FDA approval process and therefore is considering another round of private investment or alternatively, merging with a large publicly held pharmaceutical company. Elin has been asked to report to the management on the status of the patent portfolio and what is required to prepare for the diligence.

J. Elin Hartrum

- Senior Patent Counsel at CV Therapeutics, Inc. (CVT)/Director Intellectual Property at Gilead Sciences for 8 years working on small molecule programs, conducting due diligence presentations and investigations
- Transitioned from Small Pharma to Large Pharma in 2009 upon acquisition of CVT by Gilead Sciences
- Law firm (4+ years) prior to CVT; Small boutique (Reed & Associates) followed by BigLaw (Burns, Doane, Sweck & Mathis, L.L.P.)
- Education: University of Michigan (BA English, BS Math, Chemistry), Loyola Chicago Law School J.D., John Marshall Law School, LLM

Carol Cherkis, PhD

- Life Science Consultant for NewCap: 8 years
- BioInfoStrategies →Bus Dev for Early-Stage Companies

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- Head of Healthcare – Frost & Sullivan
- Corporate Ventures, Bus Dev, Marketing, R&D – Dow Chemical
- Bryn Mawr and U-Michigan – Biotechnology

NewCap Partners, Inc.

www.newcap.com

- Founded 1987
- Broker/Dealer registered with SEC/FINRA
- Middle-Market Focus ($5M-$100M); Early Companies/Special Cases
- Los Angeles, San Francisco, Silicon Valley, Beijing
- M&A, Equity Financing, Corporate Finance Transactions in China
- 7 Senior Bankers with Deep Technology and Transaction Experience, including Healthcare & Financial Services
- Industry Consultants with Experience, Expertise, and Contacts

Govind Gupta, CFA

- Principal in Ernst & Young's Transaction Advisory Services (TAS) group with a specialization in the valuation of businesses and their assets for financial reporting, tax, litigation, and strategic purposes.

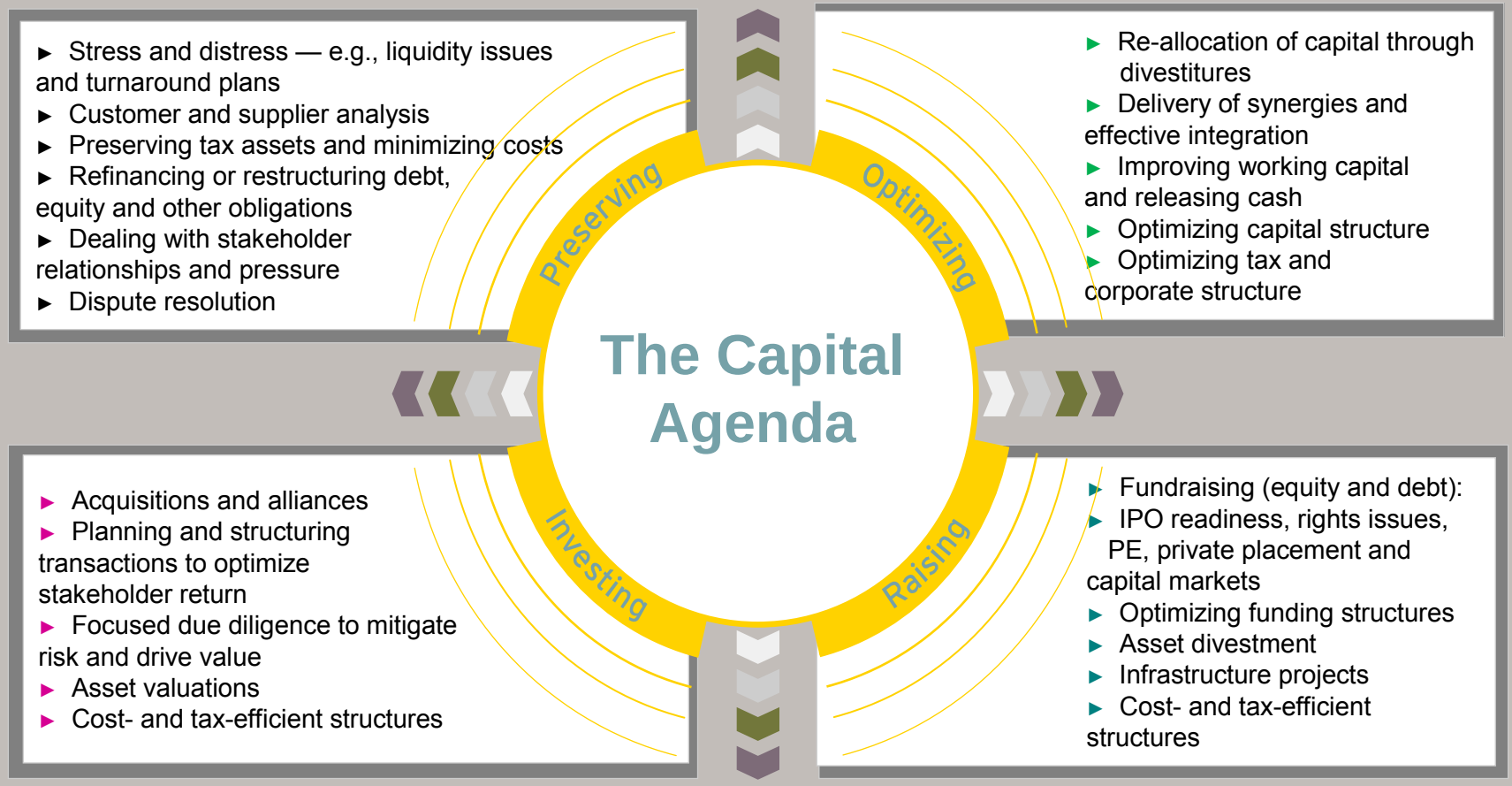
- Extensive experience in the valuation of businesses, legal entities, and individual securities, as well as the intangible assets / intellectual property within the businesses and/or legal entities.

- The Life Science industry is unique from a valuation perspective, in that the valuation of this type of business oftentimes:
  - Is based on a "sum of the parts" analysis
  - Includes an especially long projection period and may not include a "terminal value" in some cases
  - Requires an in-depth understanding of US and International regulatory standards
  - Is based on a "boom or bust" business model, with a complicated probability assessment
  - Includes projections that require large cash infusions or strategic partnerships in order to continue

The views and opinions expressed in this presentation and during this panel are those of the author and do not necessarily reflect the policy or position of Ernst & Young LLP.

Driving EY's client's Capital Agenda

How organizations manage their capital today will define their competitive position tomorrow



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Preparing NewPharma Co. for Partnering

- What are the goals for NewPharma?
  - Provide a strong basis for a maximal valuation
  - Establish credibility
  - Facilitate review (avoid being the rate limiting step)
  - Keep the budget in mind

- What to do
  - Review and clean file wrappers to look for problems
    - Fix what you can, have answers for the rest
  - Gather and double check documents: assignments, employment agreements, licenses, significant MTA's
  - Review opinions, run FTO searches and assess results
  - Create tables and presentation materials that tell your story

Due Diligence from BigPharma's Perspective

- Differences in perspective on the DD process are based in typical buyer vs. seller dynamics

- What are the goals for BigPharma?
  - Evaluate the strength and integrity of portfolio in terms of breadth and duration of IP protection in order to assess potential generic entry
  - Find the show stoppers and weaknesses in portfolio quickly
  - Focus on primary valuation point

Due Diligence – Process

- Agreements → IP Ownership

  Founder, Employee, Contractor

- Business Strategy → IP Strategy → R&D Effort

  Field of Use, Geography, On-going Search, FTO

- Preparation of IP Applications

  Filings, Budget, Firm/Attorney Choice, Deadlines

Due Diligence –NewPharma Preparation

Be able to provide good explanations about –

- Agreements related to company's ownership of IP (drug and prodrug)
- Business strategy: short and long-term
- Patents (drug), provisional application (prodrug), FTO, law firm
- Countries for IP protection and rationale
- Prodrug R&D in China: what contractor, governing law, file IP there ASAP
- Licenses, MTAs, publications/presentations

Differences upon Acquisition

- Focus and hone
- Budget still an issue but in different ways
  - BigPharm is willing to spend for offensive patenting but not so much for defensive patenting
- Scope of filings for compound protection much broader
- Prosecution is accelerated to provide longest possible PTE/SPC protection
- Filing of secondary use cases, synthesis cases, and analog/derivative cases reduced in number and size