Wednesday, May 3, 2023 Mandarin Oriental, Boston



Agenda | Wednesday May 3, 2023

Time	Agenda Item	Description
9:30 a.m. – 10:00 a.m.	Registration & Breakfast	
10:00 a.m. – 10:05 a.m.	Opening Remarks Pamela Forrest, Covington	
10:05 a.m. – 10:55 a.m.	Plenary Session One: IRA Drug Price Negotiation 201 - Strategic Implications and Key Open Questions Speakers Krista Carver (Co-Moderator), Covington Sarah Hoagland (Co-Moderator), Covington Rujul Desai, Covington Eric Rogers, Vice President, Global Pipeline and U.S. Commercial Law, Alexion Pharmaceuticals	You've heard the basics already. This is a 201-level session focused on emerging interpretations from CMS, strategic considerations for FDA-facing issues and your portfolio, and implications for life cycle planning. Topics will include: • how key FDA inputs affect the pricing provisions and strategic considerations • CMS guidance to date and to come • tools for evaluating your portfolio against the IRA • new potential market access strategies • implications for patent litigation and life cycle planning implications for licensing and collaboration deals
10:55 a.m. – 11:05 a.m.	Mini Break	

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11:05 a.m. – 11:55 a.m.	Plenary Session Two: Life Sciences Deals in 2023 - Key Trends in Capital Markets, M&A and Licensing Speakers Megan Gates (Moderator), Covington Jon Civitarese, Senior Managing Director, Investment Banking, SVB Securities Andrew Cohen, Vice President & Head Counsel, R&D Legal, Takeda Pharmaceuticals Tim Opler, Managing Director, Torreya James Schneider, Deputy General Counsel, RA Capital Management, L.P.	As we approach the halfway point of 2023, hear from industry experts on what life sciences companies need to know about financing, licensing and exit/acquisition opportunities in the second half of the year and into 2024. Topics will include: • expectations for deal activity in the life sciences market over the next year • capital raising opportunities • evaluating exit/acquisition options • examining licensing transactions
11:55 a.m. – 12:10 p.m.	CovTalk Session: Navigating the Complexities of U.SChina Relations in the Life Sciences Industry Speakers David Fagan, Covington Kim Strosnider, Covington	Hear Covington national security experts David Fagan and Kim Strosnider present on potential tighter investment and trade controls restrictions that may be coming to the life sciences sector. David and Kim will discuss legal and systemic pressures arising from the competition between China and the United States and its allies, and how those pressures may increasingly play out through investment regulation, trade controls, and other industrial policy mechanisms affecting life sciences companies.
12:10 p.m. – 12:20 p.m.	Transition to Lunch	
12:20 p.m. – 12:50 p.m.	Plated Luncheon	

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12:50 p.m. – 1:35 p.m.	Luncheon: Industry Perspectives - Bay State GC and CLO Dialogue Speakers Michael Labson (Moderator), Covington Jonathan Biller, Executive Vice President & Chief Legal Officer, Vertex Pharmaceuticals Alejandra Carvajal, Senior Vice President, Chief Legal Officer, Mersana Therapeutics Robert Hesslein, Senior Vice President & General Counsel, Voyager Therapeutics	Hear from the General Counsel and Chief Legal Officers of leading biotechnology, pharmaceutical, and life sciences companies in the region on the challenges and opportunities they see for the sector. What keeps them up at night? What industry changes do they see on the horizon?
1:35 p.m. – 1:45 p.m.	Transition to Afternoon Session	
1:45 p.m. – 2:00 p.m.	CovTalk Session: Al and ML in Life Sciences - Strategies to Minimize Risk and Maximize Opportunity Speakers Christina Kuhn, Covington Micaela McMurrough, Covington	Hear from Covington experts on the evolving U.S. legal, regulatory and commercial landscape for use of Al in the life sciences sector. What considerations should be top of mind when deploying Al to support research, product development, and regulatory submissions and responsibilities, as well as use of Al in support of traditional corporate functions, such as HR, finance and employment? What are current best practices and governance for Al programs in life sciences?

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2:05 p.m. – 2:55 p.m.	Plenary Session Three: Precision Medicine - Strategic Considerations in Drug-Diagnostic Collaborations Speakers • Stefanie Doebler (Moderator), Covington • Lesley DeRenzo, Director & Legal Senior Counsel, Vertex Pharmaceuticals • Scott Danzis, Covington • Emily Leonard, Covington	The advent of precision medicine and the increasing importance of diagnostics for drug therapies is having a profound impact on the life sciences industry. This session will discuss key questions about drugs and diagnostics: Different regulatory and decision-making inflection points for diagnostics in drug development and approval Approaches to partnerships and licensing for diagnostics and drugs Impact of regulatory and licensing approaches on pricing, reimbursement, and access Industry trends in sponsored testing programs Compliance considerations when promoting a drug with an associated diagnostic
2:55 p.m. – 3:00 p.m.	Closing Remarks Pamela Forrest, Covington	
3:00 p.m. – 4:00 p.m.	Afternoon Reception	