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COST OF CAPITAL FOR EARLY STAGE BIOTECH START-UPS FOUND TO BE IN EXCESS OF 20 PERCENT

NVCA Commissioned Research Has Broad Implications for Follow-On Biologics Debate

Washington, D.C., July 10, 2009 – The cost of capital (CoC) for early stage biopharma companies is almost twice as high as policymakers have assumed according to research conducted by Iain Cockburn of Boston University and Josh Lerner for Harvard University and commissioned by the National Venture Capital Association (NVCA). Cockburn and Lerner used various models including the Capital Asset Pricing Model (CAPM) to determine that the CoC, or hurdle rate for investors, is in excess of 20 percent. These findings, which were released today at a Capitol Hill briefing hosted by Representative Anna Eshoo (D-CA), are significant as they support a longer exclusivity period for innovators than is currently being proposed by some legislators with respect to a new Follow on Biologics (FOB) FDA approval process. The study suggests that the exclusivity period should be at least 12 years so that investors in innovation can exceed the CoC hurdle rate.

"The Cockburn-Lerner study provides hard numbers which show that the cost of capital for biotech companies is nearly twice as high as policymakers have previously assumed. These findings show that a substantial exclusivity period is necessary to enable small, venture-backed biotech companies to continue to create new life-saving drugs and therapies that improve the quality of life for so many Americans. The bill I've introduced, the Pathway for Biosimilars Act, preserves this critical pathway for innovation, promotes competition, and also saves patients, insurers, and the government billions of dollars in healthcare costs," said Representative Anna Eshoo (D-CA).

"As Congress considers the creation of a new FOB process, the central question is how to balance the public's interest in lower prices for biological drugs, with continued investment in the development of new medical treatments and cures," said Mark Heesen president of the NVCA. "We strongly support the reduction of excessive costs of biologic drugs. However, in seeking this result, we must avoid excessive damage to the system that produces the overwhelming majority of revolutionary and innovative new biologic drugs."

The Study

The NVCA commissioned the Cockburn-Lerner study because prior attempts to identify factors that drive investment in new drug development have failed to recognize the high cost of capital for small, innovative biotech companies that comprise the majority of the biotech industry. Current estimates about the cost of capital in the biotech industry are based on publicly traded companies. This substantially understates the cost of capital for the small, privately held firms because public companies are intrinsically more mature and less risky.

To assist in the study, the NVCA provided unprecedented access to proprietary venture capital databases. The report concluded that the cost of capital of the private biotech VC funded sector is at least 20% and is likely higher.

The Importance of Cost of Capital

Since the goal of any FOB system is to produce lower prices for biologics, then such a system will reduce the flow of earnings from a biologic to investors. If the reduction in the expected flow of earnings reduces the value of the earnings stream below the 'cost' of inventing the drug, investment in this area of innovation will ultimately cease

As a general rule, investments are made if the expected 'return on capital' is higher than the 'cost of capital'. More importantly, investments are not made if the return is less than the cost. If the FOB legislation has the intended result of reducing the stream of earnings from a future drug, the key question is whether the value of that 'return' has been reduced below the relevant investor's cost of capital, in this case the biotech segment of the venture capital industry.

The cost of capital and return analysis has been examined in numerous academic studies, including one commissioned by the generic drug industry,[1] a strong supporter of the proposed FOB system. That study assumed a biotech cost of capital of 10%, based on publicly traded biotech companies, and determined that on average a 'data exclusivity ' period of 7 years would permit an investor with an 10% cost of capital to make a positive return on its investment in the development of new biologics. However, according to the Cockburn Lerner study, 7 years would not be long enough to clear the 20% hurdle rate for investing in early stage companies. A seven year will drastically reduce such investments and thwart future innovation in a meaningful way.

"Since the VC community supports the overwhelming majority of revolutionary biologic drug discovery, the most innovative sector of the biotech industry will be the most adversely affected by the 7 year exclusivity period," continued Heesen. "A twelve year period will allow investors to make an adequate return and therefore continue to invest in biologic innovation while still balancing the need for lower prices for biologics."

For a copy of the study, please visit www.nvca.org.

The National Venture Capital Association (NVCA) represents approximately 460 venture capital firms in the United States. NVCA's mission is to foster greater understanding of the importance of venture capital to the U.S. economy and support entrepreneurial activity and innovation. According to a 2009 Global Insight study, venture-backed companies accounted for 12.1 million jobs and $2.9 trillion in revenue in the United States in 2006. The NVCA represents the public policy interests of the venture capital community, strives to maintain high professional standards, provides reliable industry data, sponsors professional development, and facilitates interaction among its members. For more information about the NVCA, please visit www.nvca.org.

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[1] Brill, Alex M. "Proper Duration of Data Exclusivity for Generic Biologics: A Critique" November 2008.