Conference Report

Innovation Landscape, Deal-making Strategies and Success Stories

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HE LICENSING EXECUTIVES Society (LES) held its 2015 Spring Meeting at the Hilton La Jolla Torrey Pines Hotel in La Jolla, CA (May 12-14, 2015).

As described on the web site of LES, "LES (USA & Canada) represents a highly diverse community of nearly 4,000 IP, business development and technology professionals that collaborate across multiple industries to create a unique networking and learning environment." Further information on LES is available at: http://www.lesusacanada.org

The Spring Meeting was attended by more than 200 professionals that represented companies, academic institutions, law firms and service providers. The event featured various panel discussions and workshops. Some highlights are provided below.

Mr. Mark Edwards (Managing Director, Bioscience Advisors Inc.) presented a Life Sciences Workshop entitled, "Re-emergence of Platform Technologies -- Gonna Party Like It's 1999." Mr. Edwards used the term "biotech" to refer to a biotechnology company and mentioned that a total of 150 biotechs have gone public in USA during the period of January 2013 through April 2015 (with 51 in 2013; 82 in 2014 and 17 in 2015; so far). The presentation also provided a recap of the 2000 biotech initial public offering (IPO) window. Mr. Edwards quoted a resource that reported that "biotech companies raised more money in 2000 than they had in the previous six years combined (A Superlative Year, Signalsmag.com 1/01)." The biotech public offerings in 2000 amounted to a total of \$18.5 billon, and this topped all the public offerings in the previous 8 years (1992-1999) combined. Mr. Edwards noted that "the majority (almost 60 percent) [of 2000 Biotech IPOs]" were "platform companies rather than product companies" "(2000 IPOs Lead the M&A Charge, Signalsmag.com 8/01)." Thus platform

technologies dominated the financing in 2000. Among these, 58% of the IPO biotechs were involved in genomics, proteomics/SNPs, genetics and combinatorial chemistry technologies whereas only 29% of the IPO biotechs had already developed clinical-stage drug candidates as of their IPO event. Mr. Edwards pointed out that by mid-August 2000, biotech genomic stocks were trading, on average, 99% above their IPO prices, and more than a few had tripled in value. At the end of December 2000, more than 50 public biotechs had market caps of at least \$1 billion, and 20 biotechs raised over \$200 million in a single financing. The options available to several biotechs were many; including construction of a manufacturing plant, expansion of clinical trials, recruitment of sales and marketing staff, or engagement in M&A.

However, the financing climate changed suddenly in 2001. As Mr. Edwards discussed, companies built on technology platforms were deemed to be not viable as businesses over the long term. Mr. Edward's presentation noted a resource at that time advised that "These companies are either going to have to acquire more like technology to enhance their share of the discovery platform or they're going to have to become drug discovery companies themselves by adding other capabilities." (Stelios Papadopoulos, SG Cowen, 8/01)."

In contrast with 2000, by July 31, 2001 the stocks of the 2000 IPO biotechs had begun trading on average, 30% below their closing prices at year-end; underperforming the market. Further, by July of 2002, the stocks of the 2000 IPO biotechs were trading, on average, 59% below their IPO prices. In July 2002, the aggregate market cap of the 2000 IPO biotechs plummeted to 51% of IPO valuations. Almost 50% of the biotechs that went IPO in 2000 got involved in M&A in 2001, and biotechs formed over 1,100 new alliances (with big pharma or other biotechs). However, in 2002, restructuring moves were initiated by some biotechs to protect cash; some publicly traded biotechs received warnings or delisting notices, and some other public biotechs filed for bankruptcy or liquidation. On the other hand, some of the best outcomes of the 2000 IPO companies have been InterMune (acquired

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by Roche for \$8.3 billion); Ista Pharmaceuticals (bought by Bausch for \$500 million) and Third Wave (a platform company; acquired by Hologic for \$580 million). The period of 1999 to 2003 saw that key alliances provided sustainability & momentum. For example, about \$2 billion were reported in aggregate payments with \$82 million average, and 8.3% average effective royalty rate. On the other hand, 8 bankruptcies & liquidations and 16 firesale acquisitions were reported; the latter amounting to exit at less than 50% of IPO market cap. These transactions included genomic platforms, bioinformatics, combi chemistry platform and clinical compounds.

Mr. Edwards compared the 2014 biotech IPOs versus the biotech IPOs of 2000; with respect to the % stepup per round in terms of Series A to Series B to Series C to Series D to IPO. These have been +39%; +15%; -7% and +43% for the IPOs in 2014 whereas for the IPOs of 2000, these were +92%; +81%; +48% and +103%, respectively. Comparison of the current IPO cohort with IPOs of 2000 showed that 58% of the 2000 IPO biotechs were platform technologies whereas this fraction corresponded to 41% for the biotechs that went public on US Exchanges from January 2013 through April 2015. Mr. Edwards shared that the technology platforms of the current IPO cohort include various groups such as: (1) Small molecule discovery and design, (2) Approaches to genetic and orphan diseases, (3) Protein, antibody and vaccine discovery and design, and (4) Immunotherapy, cell and gene therapy. In contrast with the biotechs of 2000 IPO when no platforms and only 29% were in the clinic, 89% of the current IPO cohort with platforms are in clinics. Mr. Edwards discussed that there have been 41 "SEC-Filed" alliances signed since January 2012 with total announced payments to the licensor of at least \$400 million, and \$22.4 billion in potential payments from recent IPO cohort alliances. The examples of post-IPO acquisitions include Omthera (by AstraZeneca), Ambit (by Daiichi Sankyo) and Prosensa (by BioMarin).

Mr. Edwards concluded his presentation with the suggestion that it is better to compete for partners than for capital and that structuring alliances could be vital for a company's future.

A Workshop entitled, "Life Sciences Global Royalty Rate and Deal Terms Survey Beyond 'BIO \$\$ Bucks'!" featured a detailed presentation by James A. McCarthy, CLP (Corporate & Commercial Development, Licensing and Alliance Management, CorpDev Ventures). This workshop discussed a landmark global survey of royalty rates and deal terms conducted in partnership by the Life Sciences Sectors of LES USA/Canada and the LES International (LESI). The results comprised deals submitted by 200+ companies out of which 128 surveys were deemed complete for analysis. About 50% the deals were submitted by companies outside of USA and

Canada. The survey is deemed useful with respect to deal terms in various therapeutic areas and geographic markets, and could be valuable in the context of early stage technologies and international deals for the present times

Based on number of deals that were submitted for the survey, the respondents corresponded to 34% notfor-profit organizations, 7% government, 49% operating companies (of these 32% were pharmaceutical and 22% were biotech), and 10% other entities. Considering organization composition, 16% of the respondents were pharmaceutical companies (including diagnostic and drug delivery companies), 19% were biotech companies (including device companies), 20% academic institutions, 7% government, and 38% other entities. Deals data analysis showed that the most prevalent therapeutic area types were anticancer (oncology), CNS, and infectious disease. Deals involving small molecules amounted to 27% of the deals. The deal statistics regarding submitted deals showed that 61% were still in the preclinical stage of development [discovery, investigational new drug (IND) track/ pre-IND, IND filed, and pre-investigational device exemption (pre-IDE)]; 80% of deals were exclusive; 78% of deals included USA whereas 64% were considered of global type. In terms of peak annual sales, 49% of deals involved more than \$US100 million. The assessment of royalty rates showed that of the 128 deals considered for the analysis, 82 deals used fixed/flat royalties, 22 employed tiered royalties, and 24 did not involve any royalty components. The average fixed royalty rate associated with the earliest stage products was about 5%. Additional inferences include potential for increase in royalties as a product matures through development, and the presence of 3 tiers as the most common structure amongst tiered royalty deals. Overall, the deals included upfront payment as the most common financial component (61%); however, sales milestones showed the greatest average and median dollar amounts. The primary valuation method used was net present value (NPV) / risk-adjusted net present value (rNPV) (45% of the deals) whereas about 32% of the deals involved the method of comparables.

Featured Luncheon Speaker Standish Fleming (Co-Founder, Forward Ventures) discussed that the pharmaceutical industry is facing innovation crisis. The key points from Mr. Fleming's presentation are described as follows. About 85% of jobs are generated through innovation. Countries that promote innovation would be expected to be global leaders. Among the factors that influence innovation, high regulation is a consideration as it can stifle innovation. The concept of innovation needs to change in that an invention without development cannot be considered innovation. In this respect, it is interesting to note that the hallmark

of 19th century was individual inventor. This changed to the hallmark being commercial lab for 20th century whereas the need for innovation marks the interest for the 21st century. Actual profits (and not simply the value of an invention on paper) are important. With respect to the trends in innovation, information technology (IT) would be important. The methods employed for financial calculations include NPV and discounted cash flow (DCF). However, these are not accurate and some risk is involved. Besides, a large fraction of innovations do not result in a product. This leads to misallocation of resources on the part of pharma. For example, in January 2012, Bristol-Myers-Squibb paid \$2.5 billion for Inhibitex (focus: Hep C therapeutic); however, wrote off a significant amount in August as the deal went bad. Thus the advice for pharmaceutical companies would be that they kill more molecules quickly and that they allocate resources for only those opportunities that show promise. In addition, Mr. Fleming mentioned that patient advocacy groups are becoming important and this can be key in the innovation space. Pharma should make parallel investments in a series of companies. Unlike some other countries, USA is risk-averse and reporting of one bad case can lead to loss of data points and that this approach needs to change.

Another highlight of the event was a Plenary Session, entitled "San Diego Success Stories Roundtable," which was moderated by Bruce V. Bigelow (Editor, Xconomy San Diego) and the participants included Alex Dickinson (Illumina); Chrysa Mineo, (Receptos) and Rory Moore (CEO, EvoNexus). The panel mentioned various examples of mergers and acquisitions deals such as those between Fisher Scientific and Life Technologies; Bristol Myers Squibb and Amylin Pharmaceuticals, and Hologic and Gen-probe. In addition, the example of Aragon Pharma's acquisition by Johnson & Johnson was discussed. Other reflections by the panel included that an acquisition can make a company lose assets and people, and thus a company may not be keen on getting acquired. In terms of the understanding of diseases, not only are the biological data important, but the bioinformatics data are also very relevant.

Overall, the LES Spring Meeting provided various panel discussions, and educational and networking opportunities for licensing and other professionals. This event is expected to facilitate continued deal-making activities within the industry and academia.