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Shareholder returns and the exploration–exploitation dilemma: R&D announcements by biotechnology firms

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Abstract

We explore a financial returns dimension of the exploration–exploitation dilemma. Using 1277 R&D announcements by 178 listed bio-pharmaceutical firms, we examine whether investors are myopic along the continuum of exploration (patenting and preclinical trials) to exploitation (human clinical trials and NDA). We find that investors respond positively at every stage, but there are differences between small and large firms. For small firms exploration is favored, provided it is focused. For large firms, there is value in both exploration and exploitation. Projects which are part of an alliance are no more likely to generate abnormal returns. Policy implications are discussed.

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1. Introduction

A key challenge facing human therapeutics biotechnology firms is how to bridge the gap in both time and resources between discovery of a compound and earnings generated by sale of approved drugs. Recent data indicate that the time taken for a drug to move through clinical trials and the process of Food and Drug Administration (FDA) approval is now 8.5 years (Tufts, 2005), with the discovery phase estimated to be a further 2–5 years (DiMasi et al., 2003). The out-of-pocket cost of taking a drug through to FDA marketing approval is estimated to be US\$ 403 million, inclusive of the cost of drugs that fail to make it through to the end of clinical development (DiMasi et al., 2003). There are three primary mechanisms by which this gap is bridged: pub-

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This paper focuses upon public-quoted entrepreneurial bio-pharmaceutical firms listed on NASDAQ and European stock exchanges. Listing provides access to capital, in addition to an exit source for venture financiers. The creation of NASDAQ in the US and changes in stock market listing rules in several European countries in the 1990s have made it possible for small (often loss-making) biotechnology firms to quote directly upon a stock exchange and thus gain access to sources of capital and innovation incentives which were

lic funding of research (Hyytinen and Toivanen, 2005); private capital in the form of venture funding or stock market listing; and revenue and cost sharing derived from inter-organisational alliances with traditional pharmaceutical firms (Rothaermel, 2001). Between 1994 and December 2006 it is estimated that the broad classification of biotechnology firms operating in Europe and North America have raised US\$ 194 billions in capital and long-term debt, of which about a third was raised from initial public offering and follow-on offerings (Biocentury, 2007).

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not available earlier (Coriat and Orsi, 2002; McNamara et al., 2000).

It has been suggested in the press and even in the academic literature that stock market investor-shareholders over-emphasize short-term earnings at the cost of longer term R&D (see Tylecote and Ramirez, 2006, for a review). This bias against long-term investment in research in, or exploration of, new technologies in favour of exploitation of a firm's current knowledge has been postulated by March (1991). If such a bias exists, it means that early stage research is disadvantaged in raising capital from the stock market. This has important policy implications.

March's (1991) theorizing that, due in part to more positive short-term returns, exploitation may drive out exploration has received mixed empirical support. Chan et al. (2001) undertook a study of all domestic firms quoted on the NYSE, AMEX and NASDAQ stock exchanges from 1975 to 1995 and found that the historic performance of firms who invested heavily in R&D did not outperform those that did not, suggesting that exploration is not necessarily associated with inferior performance. However, Hoang and Rothaermel (2006) found that the ultimate success of an alliance project is lower when initiated during the exploration stage of R&D; while, more seriously, Rothaermel (2001) found that exploitation alliances have a positive impact upon a pharmaceutical firm's new product development success, whereas exploration alliances do not. The skewed positive financial impact of exploitation over exploration activities is further evidenced in increased accounting returns generated by new product launches (Bayus et al., 2003) and also in shareholder returns (Chaney et al., 1991; Chen et al., 2002). When combined, these studies lend some support to the idea that financial returns from exploitation activities are more certain and more positive than those from exploration.

Whilst the exploration–exploitation dilemma is typically presented as dichotomous, it is clear that many writers see subtle distinctions occurring along this continuum. For example, Levinthal and March see a different valuation between "use" and "development" (1993: 105). Following the argument that exploitation drives out exploration due to clearer, more temporally proximate and larger financial feedback, the same may apply for development and use. Use activities are less uncertain in outcome than development activities and so may generate higher returns.

The theoretic perspectives of Levinthal and March (1993) are often cited in the literature; however most studies only explore the basic dichotomy between exploration and exploitation. Few studies explore the financial

impact of the micro stages that occur within each of these activities. Unpicking the micro stages may well shed light on why previous studies have been ambiguous. This paper uses the public nature of the bio-pharmaceutical industry's R&D process to explore the financial response of shareholders to announcements of positive news along six micro stages of the exploration-exploitation continuum. We classify the first two of these micro stages, namely patenting and preclinical trials, as exploration activities. We classify the remaining four micro stages as exploitation activities, namely the three phases of human clinical trials (phase 1, 2 and 3 trials) and the New Drug Application (NDA) regulatory approval process. In this industry there is a clear validation process supported by regulated bodies for each of these six micro stages of the exploration-exploitation process.

We go further than testing for a general bias against exploration; we also look for a bias against smaller firms undertaking such work. Some argue that small firms are not suited to undertake risky R&D requiring substantial knowledge and financial resources. The lack of scale and scope in smaller firms may cause them to be less efficient than larger firms in the drug R&D process (DiMasi et al., 1995). However, small firms may have a comparative advantage in early stage R&D because they are nimble and flexible (Powell, 1998).

The paper begins by exploring these arguments in some detail from a theory perspective. We then examine empirically how investor-shareholders value R&D investments in bio-pharmaceutical firms' R&D process. Our data set contains information on 1227 announcements of the initiation and progress of stages of R&D projects by 178 entrepreneurial bio-pharmaceutical firms listed on US and European stock markets between 1996 and 2003. It provides encouraging evidence that the typical investor in stock markets is not so myopic as to ignore the value potential of exploration and that they see the value of smaller firms undertaking early stage work. We consider the implications of our findings for the strategies of small and large firms. We also comment on the value of institutional policies that can be introduced to assist firms in their access to capital from stock markets.

2. Theory and hypothesis development

2.1. Exploration–exploitation theory

It was March (1991) who explicitly discussed and classified managerial search behavior on an exploration–exploitation continuum. In his modeling, he makes the claim that managers will be biased against exploratory search because "[t]he certainty, speed,

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