1. Introduction: international entrepreneurship in the life sciences

Marian V. Jones, Colin Wheeler and Pavlos Dimitratos

INTRODUCTION

Why is international entrepreneurship important to the life sciences industry and why would international entrepreneurship scholars be interested in research focused on one specific industry context? These are the two fundamental questions that brought a number of the authors of this book together to discuss what interests us in research on life science-based ventures, and how we might take that research forward in research agendas of interest and value to the industry community, as well as to those whose business is to pursue and advance knowledge for scholarly purposes.

The life science industry, on which many national and regional economies have placed their hopes for growth, consists of a great number of very small, specialized firms with very uncertain futures. Life science small ventures, which perform a range of highly specialized and interdependent roles within a complex and potentially global industry, face considerable challenges with regard to their survival and growth.

For science or technology-based new ventures long product development lead-times are often coupled with very short windows of opportunity in an industry characterized by rapid technological change and intense competition, where advances towards open innovation are coupled with the restrictions of what is a highly regulated industry. Resources for development may be in short supply or difficult to access. For these reasons new ventures need to be resourceful, innovative and creative, alert to opportunity, able to build and exploit their core competencies and develop mindsets and capabilities that encourage successful operation in a global industry.

New ventures that are established to exploit a technological innovation need simultaneously to pay attention to and balance the entrepreneurial process of establishing and growing a firm, with the innovation process

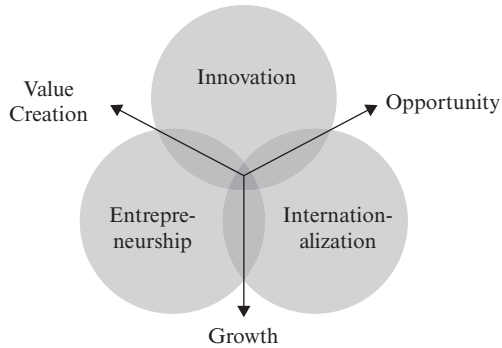

Figure 1.1 Potential gains at the interface between innovation, internationalization and entrepreneurship processes

through which their technology is commercialized, and with the process of internationalization to establish positions in local and global markets for knowledge, technology, resources and customers. These processes – entrepreneurship, innovation and internationalization, for ventures established to exploit a scientific or technological innovation, in an industry that is essentially global – are inextricably intertwined. Together they drive towards opportunity, value creation and growth. Navigating these processes in the uncertain and relatively uncharted waters of the life sciences industry is not straightforward, nor easy to comprehend either for those immediately involved in the industry, or for those trying to understand it. Where these processes are interlinked and coordinated lies potential for the discovery and realization of opportunity, the creation of new value and prospects for growth as illustrated in Figure 1.1.

Amongst our aims for this volume is for it to stimulate a sector-specific discussion on small and new-venture firms in life sciences. The key themes underpinning the chapters are innovation, entrepreneurship and internationalization. The book is cross-disciplinary to the extent that, while international entrepreneurship is the central theme, the chapters take different perspectives drawing on strategic management, economics, entrepreneurship and international business. We intend that the book will stimulate further research, including cross-national and cross-disciplinary research on international business venturing and, in taking a context-sensitive and sector-specific approach, will draw attention to relevance, and applicability to practitioners in management and policy. Thus our focus is on the life science sector and we hope that other international entrepreneurship authors may compile similar context-focused volumes on other sectors, countries or contexts within which international business venturing takes

place. Understanding how firms behave in such complex environments relies on an appreciation and recognition of the context in which they operate. In this introductory chapter we outline life sciences as an industry sector, introduce international entrepreneurship as an integrative perspective and describe the contributions from the chapter authors.

THE LIFE SCIENCES AS AN INDUSTRY SECTOR

Industry Background

Life sciences as a sector is best described as a complex amalgamation of interconnected industries comprising a diverse range of knowledge-intensive and often highly specialized firms. It includes firms in the fields of biotechnology, pharmaceuticals, biomedical technologies, life systems technologies, nutraceuticals, food processing, the environment, biomedical devices and organizations that are involved in the various stages of research, development, technology transfer and commercialization.[1] Life sciences such as biotechnology tend to be defined at the R&D end of the value chain by the basic science driving the sub-sector, for example molecular biotechnology (Bartholomew, 1997), by the discipline and/or service provided (such as bio-informatics at the production phase of the value chain) or by the commercialized output at the market or distribution end (for example medical devices). For this reason the sector is more often described as Biotechnology or Modern Biotechnology, taking its name from the discipline driving the science rather than the more generic term Life Science. Biotechnology is often further sub-divided according to its application: for example *Red* biotechnology is concerned with human health, drugs, drug discovery and diagnostics, *Green* relates to the environment and agriculture, *Blue* to the marine environment, management of fish stocks and bio prospecting and *White* to improvements in industrial processes such as the replacement of chemical fuels with biofuels. These areas of focus are neither mutually exclusive nor discrete, however, and bio prospecting in the marine environment increasingly results in drug and treatment discoveries and developments in human health (Evolution Life Sciences[2] and Biology Online[3]).

Life sciences and modern biotechnology in particular are seen as amongst the key enabling technologies of the twenty-first century promising potential applications in many sectors and the prospects for a cleaner, healthier world. The life sciences industry is significant in the goals of the EU's Lisbon Strategy towards climate change, clean energy, public health and sustainable consumption and production in an economy directed

towards sustainable economic growth, better jobs and social cohesion (European Commission, 2005). Despite its promise, however, the industry is complex and hard to understand, difficult to navigate for new and entrepreneurial firms, and in many respects has failed to date to realize the products, processes and economic growth anticipated (Zika et al., 2007).

The Global and Local Context of Life Sciences

The biotechnology industry is relatively young, emerging in the USA in the 1970s mainly in the San Francisco and Boston areas. By 2007 Ernst & Young reported that it had developed into a truly global industry with presence in the USA, Europe and Asia, of which Europe accounted for 15 per cent of global revenues. Between 2007 and 2008, despite the recession, global revenues continued to rise but less slowly in the EU and the USA whilst elsewhere growth continued to be strong: for example, Australia saw a 26 per cent increase in revenues between 2007 and 2008 (Ernst & Young, 2009a). While demand for biotech products is now globally widespread, upstream R&D and innovation activity are increasingly located in countries outside the EU and the USA and growing biotechnology sectors are now notably evident in Australia, Japan, India, Brazil, Russia, China and South Korea (Zika et al., 2007). A report from Ernst & Young's Global Pharmaceutical Centre (2009) reported the world's fastest growing pharmaceutical markets to be China, Mexico and Brazil and many countries are encouraging inward investment in the industry through modernization and reform. Reforms in clinical trial procedures, standardized approvals, product safety and regulatory pathways in India and China and reform of regulatory structures in Japan are stimulating outsourcing of specialized activities to those regions and contributing to the growth of their life science industries (Ernst & Young, 2010). China and India were emerging as important centres for innovation with growing biopharmaceutical capabilities due in part to their much greater output of science and technology graduates than the EU and the USA (Zika et al., 2007).

The life science industry today can be described as a globally networked arrangement consisting of pharmaceutical companies which tend to be large, well established multinational organizations in dominant positions in the global industry, often referred to as Big Pharma, and an extremely large and varied range of biomedical, drug, diagnostic, device and service companies. The term *biotechnology industry* is now generally used to refer to small or start-up companies founded to exploit inventions in the life sciences, and biotechnology may be defined as 'the use of cellular and molecular processes to solve problems or make products' (Mehta, 2008, p.4). Many of the smaller firms are university spin-offs or independent

start-ups founded on the basis of technology from established firms or public research laboratories (Shane, 2004). Life science and biotechnology new ventures are of particular interest in this volume because of their position in relation to Big Pharma and the local and global juxtaposition that characterizes their inter-relationships and competitive postures in the global industry.

The Process of Innovation in Life Sciences

> Innovation is the process of converting technological advances or inventions into new products or product attributes with the goal of creating demand and increasing market share (Kuemmerle, 2006 p. 313).

It may be further distinguished between technological and non-technological innovation and product and process innovation (OECD, 1992, pp. 27–9), and may be incremental, radical, continuous or discontinuous. In new biotechnology firms, innovation is (at least initially) '. . . the process whereby a discovery is taken to the market for some commercial outcome' (Milsom, Hine & Kapeleris, 2006, p. 35). It involves the creation of new value and intellectual property for which rights may need to be registered. Biotechnology firms often emerge from or consist of an R&D process from which one or more technologies are commercialized, alone or in partnership with other firms or organizations. The process of taking a technological innovation from the laboratory to the market may involve one or many firms and organizations as each stage may require highly specialized knowledge and capabilities. The value chain from laboratory to market for a biomedical device may include at least three stages. Typically these would be: (1) the discovery and pre-clinical trials stage involving the development of a product concept, device specifications and design, and animal testing, (2) clinical trials which usually extend to three stages: production prototype, pilot trial and pivotal trial, and (3) manufacturing, marketing and sales (Mehta, 2008). A firm might not perform all of these stages itself, however, as its own value chain may be 'embedded in a larger stream of activities within the value system of the industry' (Hine and Kapeleris, 2006, p. 184). This value system or network may extend across several organizations and several countries with key stages in the innovation process of any product being outsourced to global locations where there is the available expertise, at reasonable cost and quality, and an appropriate regulatory environment. Regulatory pathways can be complex, involve multiple stages and extend the development time of any biomedical device or biopharmaceutical product to 12 or more years.

At national level the innovation process is often orchestrated by a

country's national innovation system (Bartholomew, 1997). National and regional innovation policies have tended to encourage the clustering of life science firms in specific locations where they may benefit from proximity, critical mass and, most importantly, the sharing of knowledge and capabilities. The knowledge intensity of innovation at the leading edge of bioscience means that knowledge and capabilities are highly specialized and also locally 'sticky' (von Hippel, 1994), developing around a core located in clusters surrounding universities, publicly funded research laboratories or established pharmaceutical companies. These trilateral, networked relationships are described as the Triple Helix innovation model (Etzkowitz and Leydesdorff, 2000), which relies on collaboration or at least communication amongst various organizations to bring highly specialized and potentially co-dependent or co-specialized bodies of knowledge and capability together towards product development. Because expertise in clusters tends to be highly specialized and specific to a narrow range of technologies, there is a need for knowledge sharing between specialized clusters of innovation activity at local and global levels. This has led to calls for *open innovation systems* (Chesbrough, Vanhaverbeke & West, 2006) in which inflows and outflows of knowledge are encouraged to accelerate innovation and expand innovation markets. Today ideally even the smallest and newest firms in life science need to interact and inter-relate with other players in what is rapidly becoming a globally networked industry. The ability to internationalize early to access knowledge, resources and ultimately markets is imperative.

Business Models in Life Sciences

The length and complexity of typical life science innovation or value chains, together with regulatory requirements from government agencies such as the FDA[4], the EMA[5] and the TGA[6] is a major reason for the diversity of business models prevalent in the life sciences industry. A business model is generally regarded as the design of the business, or a framework to support its business processes towards value creation and profit generation. The most frequently cited components of business models include the firm's value offering, economic model, customer interface relationship, partner/network roles, internal infrastructure/connected activities and target markets (Morris, Schindehutte & Allen, 2005; Onetti et al., 2010a and 2010b). The business models of firms involved in international business tend to be described in the extant literature by reference to the geographic location of their value-adding activities and the applied forms of governance, such as exporting, licensing and foreign direct investment. In the life sciences industry, business models tend to be described in relation

	R&D	Regulatory process e.g. clinical trials	Manufacturing	Marketing & Distribution
Do it yourself				
Partnerships or alliances				

Source: Adapted from Mehta (2008, p. 97). A firm and/or its activities may extend across one or more boxes, so a fully integrated company would extend to the whole value chain whereas specialized firms will focus on a shorter section.

Figure 1.2 The innovation/production value chain

to the firm's role in the industry innovation or production value chain and range from being narrow and highly specialized to fully integrated. Mehta (2008, p. 97) describes a business model in the context of biomedical technologies as:

> . . . the means by which an organization generates revenues and profits from an innovation and resultant products. A business model also defines the product (to some extent), positions the company in the value chain (product commercialization process) and describes the mechanisms of getting revenues from the product over time.

Life sciences business models are further defined by the length of their value chain or the breadth of applicability of their products/services across one or several industries (Figure 1.2).

Innovator firms focus on the first stage in the value chain, so for example drug discovery companies often focus on R&D but if successful may over time become fully integrated pharmaceutical companies extending to the full length of the value chain. Firms with 'platform' technologies (for example innovators of devices and diagnostics (tests) with wide applicability) tend to focus on a specialized part of the value chain but extend their products or services horizontally across a range of product applications, companies or industries. Some research suggests that as bioscience firms mature they may adapt or radically change their business model from that designed to promote their initial technological capabilities to one more relevant to new opportunities discovered as they develop business capabilities (Brink and Holmén, 2009).

The global recession commencing in late 2009 has put various pressures on the venture capital industry, on which early-stage firms in particular rely; so, traditional life science business models are changing in response. Other challenges include political debate in many countries about who should pay for healthcare and how bioscience and the development of

drugs and treatments should be funded. Expiries of patents from some of the earliest biopharmaceutical innovations and the resultant surge in generics has forced many pharmaceutical companies to re-examine their business models as pressure on product pipelines increases (Ernst & Young, 2009). This is anticipated to change the structure of the industry and the role that has been played by small firms to date.

The Importance of Small Firms in Life Sciences

Empirical evidence has consistently shown that small firms are responsible for more innovations than larger firms (Acs and Audretsch, 1988), that they are more likely to produce radical innovations (Scherer, 1984), and that firms with strong academic links are more likely to introduce innovations (Lerner, 2004). Small, innovative biotechnology companies achieve a greater number of product approvals than does Big Pharma despite the significantly higher investment by the latter in R&D (Ernst & Young, 2007a). Being the drivers of innovation small firms are important to the industry as independent innovators, as partners to other firms and as targets for acquisitions. Firms in biotechnology are often small, specialized organizations: for example dedicated biotechnology and drug discovery firms (Mehta, 2008). They are often university or research laboratory spin-offs which have close links with academia and are established explicitly to exploit a technological innovation. Small firms have advantages over large ones in innovation, amongst which are flexibility, autonomy and connections with community activity: for example in local innovation clusters (Kuemmerle, 2006). The knowledge intensity of innovation at the leading edge of bioscience means that complementary and co-dependent knowledge and capabilities often develop in clusters around a core consisting of universities, research laboratories and established pharmaceutical companies (Powell et al., 2005). Such knowledge may be highly specialized within each cluster, which results in geographical separation between local clusters of knowledge and fragmentation in the global industry hindering product development and requiring innovative business models. For these reasons alliances in the industry are common and cross-national, and acquisitions of early-stage biotechnology firms have commanded a premium price (Ernst & Young, 2007a). For the same reasons new-venture biotechnology firms need from inception to be aware of research and business activity in both the global and the local arenas.

While small firms are important in life sciences, many of them fail. Small life sciences companies are often founded on the basis of promising scientific or technological inventions or discoveries (Hine and Kapeleris, 2006). However, few biotech companies are successful since they are based on

the potential outcomes of 'unrealised discoveries' and as Ernst & Young (2007a, p.1) express, they are often:

> . . . cobbled together by entrepreneurial scientists and sustained more on vision and ambition than commercial experience. [However] the entrepreneurs who create biotech companies are driven more by the desire to harness innovation for improving human lives than by aspirations of financial gain.

For reasons already discussed, including the global demand for products from biotechnology and the globally spatial diversity of the industry's knowledge base, biotechnology companies have to think global from day one and irrespective of age or size 70 per cent of firms surveyed in the Ernst & Young Biotech CEO Survey (2007b) anticipated that they would expand globally within two years. Mergers, alliances and outsourcing of key activities were all anticipated as challenges facing the industry.

Further challenges are anticipated that may impact the growth and development of smaller firms (Ernst & Young, 2010). Big Pharma is examining and redesigning its business models and some companies are restructuring their R&D units along the lines of biotech firms to stimulate innovation by giving their teams of scientists more autonomy. Outsourcing, particularly of clinical trials to countries outside the USA and Europe, is becoming common as large firms attempt to maximize the benefits of their global networks. The race for blockbuster drugs which has previously driven industry growth is under pressure following the simultaneous expiry of many patents from early discoveries. As a result there is more focus on pipeline decisions and who will pay for developments.

The Ernst & Young (2010) Global Report suggests several impacts on smaller firms, including their popular goal to become fully integrated pharmaceutical companies, and raises questions as to the extent to which they can be profitable as specialized rather than integrated units. In response to global changes Ernst & Young call for the development of fully integrated pharmaceutical networks (FIPnets) as underpinning strategies that draw together emerging markets, and complementary products and services. They also suggest investment in people and talent which they contend has tended to be neglected in favour of the R&D, discovery and product pipeline. Pressures such as these suggest that life science firms, both large and small, need to be entrepreneurial in outlook, globally oriented and connected in both science and business. Rather than a gradual and optional development route, internationalization is increasingly an immediate imperative in the life science industry where capabilities in international entrepreneurship would seem to be at a premium. While

these issues present considerable challenges for the firms, they represent a rich landscape for research in international entrepreneurship.

INTERNATIONAL ENTREPRENEURSHIP: INNOVATION, ENTREPRENEURSHIP AND INTERNATIONALIZATION

International entrepreneurship as a field of study is often attributed to the emergence of firms now generally known as international new ventures (INVs). Observed in the mid to late 1980s these were often small, young firms that were able to become involved in international business almost from inception. Predominantly, reports on early internationalizing firms came from studies of small high technology firms amongst which were IT, biotechnology and other knowledge-intensive firms from new and emerging technology sectors. These science-based firms were not only responding to globalization forces including rapid technological advances and economic integration, they were also, through their role in technological advancement and innovation, playing a part in driving globalization. The phenomenon of early internationalizing firms corresponds temporally with the early development and globalization of the IT and biotechnology industries.

Initially international entrepreneurship was primarily concerned with theoretical developments in explanation of early and rapid internationalization (Oviatt and McDougall, 1994; Jones, 1999; Bell et al., 2003; Jones and Coviello, 2005) and with the types of firm (Knight and Cavusgil, 1996; Madsen and Servais, 1997) or strategies that enabled small and young firms to behave in those ways (Ibeh and Young, 2001). It was defined by McDougall (1989, p.387) as:

> . . . the development of international new ventures or start-ups that, from their inception, engage in international business, thus viewing their operating domain as international from the initial stages of the firm's operation.

International business theories on internationalization – including economic-based approaches such as internalization theory and transaction explanations of entry mode choices (Buckley and Casson, 1976), and internationalization process theories (Johanson and Vahlne, 1977), together with approaches from innovation-based theories of the growth of the firm (Acs and Audretsch 1988; Penrose, 1959) and from entrepreneurship provided the foundation for this developing school of thought and in 2000, McDougall and Oviatt (p. 903) advanced a definition

of international entrepreneurship (IE) accommodating entrepreneurial behaviour and value creation with internationalization as:

> . . . a combination of innovative, proactive and risk-seeking behaviour that crosses or is compared across national borders and is intended to create value in business organisations.

The core concepts from entrepreneurship theory of new value together with opportunity discovery or creation, pursuit and exploitation (McDougall, Shane & Oviatt, 1994) have increasingly become influential in explanations of the behaviour of certain small firms, particularly science-based firms in their international business activities, or response to globalization pressures.

Historically innovation has also provided a theoretical basis for explanations of internationalization in which each new country entered, or each new entry mode adopted is considered an innovation for the firm. The process of internationalization through events and processes triggered by or emerging from innovations was compared to the process of entrepreneurship by Jones and Coviello (2005, p. 289) as:

> . . . [an] evolutionary and potentially discontinuous process determined by innovation, and influenced by environmental change and human volition, action or decision.

Thus in this definition, drawing from one similar on the entrepreneurial process (Brazeal and Herbert, 1999), the entrepreneur is distinct from the innovation in that it is the entrepreneur whose behaviour directs or creates the innovation on which the process of development rests.

Now, a decade into the twenty-first century the world is significantly more globalized and early international activity by small firms is more the norm than the exception. While interest in internationalization and the types of venture that are able to internationalize early and rapidly continues to dominate IE as a disciplinary domain, increasingly studies are emerging that address issues relating to the resources and capabilities that underpin internationalization, and factors that enable small and new ventures in global industries and markets to compete and sustain their activities over time. Thus the resource-based view (RBV) and capabilities perspectives influence recent studies in international entrepreneurship (Sapienza et al., 2006; Zahra, Ireland & Hitt, 2000) and entrepreneurial economics, institutional theory and economic geography further extend its cross-disciplinarity and scope to explain the entrepreneurial behaviour of firms in an international context (Yeung, 2009). To the extent that life science new ventures can be described as international new ventures, their

study will further advance the field, and contribute valuable insights and directions for management and policy.

THE SCOPE AND AIMS FOR THIS VOLUME

The aims for this volume are to contribute to a discussion and research agenda concerned with the start-up, competitiveness and growth of life science ventures in the local and global contexts of the industry and markets. This is achieved through a collection of empirical and conceptual research papers written with an intention to establish a dialogue between practitioner, policy and research communities, containing evidence and perspectives from contributors and studies from a number of different countries. The authors are from several countries. The chapters report on research studies from Australia, Denmark, Finland, Italy, Scotland, Switzerland and the USA. Topics covered in this volume address contemporary challenges of relevance to life science firms and draw on leading-edge debates in international entrepreneurship research such as the nature of the born-global firm, the development of international capabilities and competencies, the role of local and international partnerships and alliances, competitiveness, opportunity recognition and orientation, and the role of specialized complementary assets in internationalization. Institutional and policy influences at the level of the firm, network and industry are featured in several chapters. The chapters are presented in four parts relating to (1) new venture attributes and international capabilities; (2) the role and establishment of partnerships; (3) developing capabilities and competencies for internationalization; and (4) growth, performance, and internationalization.

Part I: New venture attributes and development capabilities

The market for life science firms, especially those in the biotechnology and medical device sectors, is global and reliant on knowledge and expertise which may be located in geographically dispersed centres of excellence. The long-term survival of life science SMEs and the local economies in which they reside relies on their ability to internationalize early, establish international partnerships and secure contracts with major international companies.

These challenges underpin the research questions addressed by Jones, Wheeler, Dimitratos and Vlachos (Chapter 2) in their assessment of the internationalization capabilities of new ventures at or soon after start-up. Drawing on the INV/born-global literature together with constructs from the RBV and dynamic capability theories, they examine the extent

to which the ventures are international, or have the capabilities and competencies that underpin early involvement and competitiveness in a global industry. Attributes identified with born-global firms provide the analytical framework which comprises: (1) the speed with which the firms commence international trade; (2) their competitiveness and potential for growth in the international arena; and (3) their ability to build and maintain networks. Evidence suggests that while some firms enter international markets very early, attributes beyond their founding technological innovation that are relevant to international growth are present in varying combinations and degrees across the firms.

Renko, in Chapter 3, investigates differences in the strategic orientations of Nordic and US-based young biotechnology ventures. These firms are simultaneously affected by strong global and local forces which are reflected in the strategic orientations – like market, entrepreneurial and technological orientations – adopted by the ventures. The study compares a sample of Silicon Valley-based biotechnology ventures with biotechnology firms of similar age and size in Northern Europe (Finland and Sweden), and in the South Florida and Philadelphia areas in the United States. Altogether, 85 firms are analysed. The results show that, while ventures' market orientation remains similar regardless of their location, other aspects of firms' strategic orientations do differ from one geographic area to another. Renko suggests that these differences predominantly reflect the institutional environments and resource endowments specific to each location.

In Chapter 4 Pregelj, Verreynne and Hine point out that the role of small, entrepreneurial firms, operating in the global life sciences and related pharmaceutical and biotechnology industries, has often been overlooked. Instead attention has been paid to the role of larger, multinational firms and their ability to advance new products through the research and development pipeline efficiently and rapidly due to their competencies and economies of scale. The authors advance evidence that, while larger firms do develop new products rapidly and efficiently, smaller pharmaceutical and biotechnology firms are equally efficient and rapid. These firms utilize their networks, collaborations and organizational learning mechanisms to build the capabilities required for efficiency and rapidity through the development process. Over time these capabilities become increasingly specialized, allowing the firms to establish an equal standing in a highly competitive global market.

Part II: The role and establishment of partnerships

Nummela and Nurminen discuss the formation of partnerships by small biotech companies in Finland (Chapter 5). Partnerships may help small biotechnology companies to diminish or even overcome the major

liabilities associated with internationalization. This study explores partnership formation among such companies, reflecting the focus of the Finnish sector on health biotechnology because of its economic significance and future potential, and because of the inherent risks in this sector associated with the long and expensive product-development process. Partnering, the authors find, is driven by internal, external and social factors, with the main motives varying with the stage of new product development. They analyse three types of partnership (exploration, examination, exploitation) in the light of a theory-based framework incorporating the different motives, the new product development process, types of partnership and potential partners.

Collaborative entrepreneurship and internationalization in life sciences by Italian biotech firms is the focus of Chapter 6 by Zucchella and Kabbara. The concept of collaborative entrepreneurship is borrowed from Miles, Miles and Snow (2006) and addresses the need for effective and continuous innovation, through a better utilization of knowledge leveraging interfirm networking. In biotechnology the pressure to generate innovations and the attitude towards networking are among the key features of the industry. Biotech firms are characterized – usually from their inception – by multiple collaborations with different actors both on a local basis within local biotech clusters, and globally. Collaborative entrepreneurship in biotech is considered in this chapter as one of the key elements of the biotech business model to support the exploration and exploitation of opportunities by new/young dedicated biotech firms (DBFs) across countries. The empirical findings are drawn from an Italian data set and relate to 52 biotech firms (from the 260 biotech firms reported in Italy), and a longitudinal case study explores deeper the patterns of domestic/international collaboration and their evolution over time. The authors find that biotech new ventures which have an international orientation (and thus better growth perspectives) also have stronger local links. They suggest that the entrepreneurial biotech organization is 'naturally born global', and grows globally through collaborations, both social and inter organizational. The social and interorganizational ties are deeply embedded in the international entrepreneurial pattern of these firms and evolve over time through reciprocal relations.

The contribution of alliance-driven governance to regional development in the Scottish life sciences sector is the concern of Birch and Cumbers in Chapter 7. Less-favoured regions (LFRs) in developed countries face a number of difficulties resulting from a shift towards knowledge-based sectors like the life sciences. Uneven development of the knowledge economy means that these LFRs lack the basic infrastructure needed to attract and embed new employment. Furthermore, the extent of LFRs'

international linkages means that they are unlikely to attract new investment to alleviate this uneven development. These international linkages, and the form they take, are vital when considering the regional development of LFRs in a knowledge-based economy. Using a global commodity chains approach, this chapter illustrates the importance of international linkages to the Scottish life science sector and considers how new 'alliance-driven' relationships contribute to regional development in an LFR.

Part III: Developing capabilities and competencies for internationalization

In Chapter 8 Rasmussen, Hannibal, Lydiksen and Servais present a case-based study of two Danish university spin-offs that are sub-suppliers in the life science industry. As with many (and perhaps the majority) of biotech firms the two firms studied come from university research and can thus be labelled as university spin-offs. Both firms are sub-suppliers to both industry and academia and could be expected to follow the same strategy to a large extent. But in fact they have adopted very different strategies regarding production, innovation, marketing, networking and, especially, with regard to how to preserve and develop their competitive advantage. To a large extent they face similar challenges, but develop their capabilities and make themselves dynamic in very different ways. Both firms have their roots in the university world and have tried to reach out to the commercial world by selling products and services. Both firms (though their strategies are quite different) have tried to balance between these two worlds. One firm is embedded in the university setting and, as its founder is both a professor at the university and the CEO of the firm, it is difficult to distinguish the influence of their different agendas. The authors argue that this firm has some difficulties in reaching out to the commercial market thus impeding its growth. In contrast the other firm moved from the university campus many years ago and presently it needs to establish new contacts in the university. Absence of academic linkages is a barrier to its continued growth.

Two further case studies, this time from the USA and the UK, are the focus of Warner and Carrick in Chapter 9. Taking a resource-based view (RBV) they examine issues relating to the rapid internationalization and sustained competitive advantage of two life science INVs. Applying the Hitt, Ireland and Hoskisson (2005) RBV framework, they examine life science INVs' *tangible* and *intangible* resources to assess rapid internationalization and sustained competitive advantage. At the firm level, findings suggest that the US and UK life science INVs are similar, in that they are both rich in intangible resources and that this knowledge has facilitated rapid international growth and sustained advantage. At industry level, results show life science funding models inherently differ between the USA

and the UK and the availability of capital impacts on survival, growth and internationalization.

The importance of intellectual property protection for three Swiss life science SMEs further enhances understanding of the specific challenges faced by individual firms. In Chapter 10 Keupp, Friesike and Gassmann examine the under-researched question how internationally active SMEs protect and appropriate rents from their intellectual property (IP), and how this protection should be implemented. Their exploratory study is a welcome contribution to extant literature on international entrepreneurship which to date has paid little attention to how companies protect their IP, despite recent contributions highlighting that the basis of these firms' competitive advantage lies in their unique knowledge, which needs to be protected against outflow and imitation. The authors relate the extent to which these SMEs appropriate economic returns from their IP to the firm characteristics. Findings point to seven endogenous and exogenous influencing factors: financial resources, experience with infringements, collaborations, market strategy, technology's risk of imitation, the market's competitive structure and technological level.

Their findings further suggest that SMEs should protect their IP with both legal and formal protection strategies and adopt a high degree of professionalism with respect to IP protection.

Part IV: Growth, performance and internationalization

In Chapter 11 Wheeler, Jones, Vlachos and Dimitratos discuss performance trade-offs (success, revenue and profitability), continuing the study of firms in the Scottish life sciences industries reported in Chapter 2. In this chapter they explore the internationalization process and its wider impact on firms, examining conventional performance indicators and identifying other indicators relevant to the internationalization process. As life science new ventures often do not perform well according to conventional performance measures, especially in the first years where revenues may be scarce or non-existent, the authors' research questions relate to the appropriateness of conventional measures in capturing internationalization and performance, and how firm founders perceive the successfulness of their ventures. Building on a framework developed by Manolova and Manev (2004) to analyse research on internationalization and the overall performance of the firm, they conclude that traditional performance indicators do not capture the performance of the firm or the impact of internationalization on it. Importantly, some performance measures (especially those externally imposed) may diminish the achievements of a firm.

Performance continues to be the theme in Chapter 12 in which Ujjual empirically examines the internationalization of life science firms and

the dynamic interaction between networks, innovation and export performance. Hi-tech firms internationalize rapidly, as there is less scope domestically for their operating niche. Owing to their global nature they encounter international pressures earlier, rather than evolving through a series of international stages, affecting such as global products, sources, and competition. The effective use of resources and networks is extremely important, as acknowledged in the international entrepreneurship literature, but largely ignored in the export literature which has tended to focus on internal factors. Innovation capabilities are also under-explored and results are inconsistent. Using an export performance model as an integrative framework, this research determines the critical internal and external factors, and the extent to which they differ in their impact on exports to different destinations. The results show that final export destination modifies the set of determinants, because export performance is multifaceted, and also because the specific target export market requires a unique range of capabilities.

Brännback, Carsrud and Kiviluoto pose an intriguing question in the title of Chapter 13, '*Firm growth and performance in biotechnology: financial facts or wishful thinking?*' Firm growth and performance have attracted the interest of researchers and the public press for decades. However, research findings on the relationship between growth and profitability are inconclusive and recent research findings challenge assumptions that have almost been regarded as accepted wisdom. Moreover, the field of biotechnology has commonly been considered *a* high technology and high growth industry with enormous profit potential. However, studies on privately held, small start-up firms with respect to growth and firm performance are extremely rare. Most studies concern publicly traded biotechnology firms, which account for a fraction of the field. Moreover, many studies are at industry level and are not concerned with firm-level performance. This chapter shows that firm growth and profitability can be particularly painful issues for young start-up biotechnology firms.

In Chapter 14, Dimitratos, Jones and Wheeler present a theoretical framework of decision-making processes for internationalized life science firms, which is an important and under-investigated aspect of the activities of internationalized firms in life science sectors. Drawing on the strategic management and international entrepreneurship literature streams, they advance a model capturing the antecedents, characteristics and consequences of international decision-making processes in life science firms. Such decisions include initial entry to international markets, mode switching decisions and commitment of resources to internationalization. In line with key issues in international entrepreneurship, and pressures on firms in the life sciences sector, the motive and urgency of decisions is paramount.

In conclusion, Chapter 15 summarizes the contributions and advances an agenda for future research.

NOTES

1. http://www.infoport.ca/life/bins/content_page.asp?cid=4364, accessed 22 March 2010.
2. http://www.evols.co.uk/index.php/innovation/e_library/by_category/industry/, accessed 14 June 2010.
3. http://www.biology-online.org/, accessed 28 July 2010.
4. FDA – the Food and Drug Administration, USA: http://www.fda.gov/.
5. EMA – European Medicines Agency, Europe: http://www.ema.europa.eu/.
6. TGA – Therapeutic Goods Administration, Australia: http://www.tga.gov.au/.