Life sciences acquisitions and divestments

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Introduction

According to BDO South Africa:

> *The private equity industry stands at the beginning of a new decade with more dry powder on hand than ever—$1.5 trillion—thanks to record fundraising in 2019. However, with ongoing rumblings of an economic downturn and continued aggressive competition for quality deals, deploying that capital is getting more, not less, challenging.*(1)

This raises the questions of what a private equity or venture capital investor looks for in a life sciences investment and what should a divestment strategy for a life sciences business include.

To establish a portfolio of investments, BioVentures, South Africa's first niche biotechnology and life sciences venture capital fund, looked for South African start-ups with:

- proprietary technology that gives them a competitive advantage;
- a large, growing and preferably international market;
- multiple products and markets rather than a single product and market; and
- a quality and balanced management team.(2)

This article considers these points in more detail to create a checklist for divestiture preparation or asset hunting.

Proprietary technology that gives companies competitive advantage

Companies which sell non-regulated products or services can generate revenue fairly quickly and protect much of their investment. However, life sciences companies typically operate at a loss or generate no revenue for a long time (eg, 10 to 15 years for pharmaceuticals).

A distinguishing feature is the necessity for national regulatory approval to market a product in a particular jurisdiction. In this regard, the South African Health Products Regulatory Authority (SAHPRA):

- monitors, evaluates, regulates, investigates, inspects, registers and controls medicines, scheduled substances, clinical trials and medical devices, *in vitro* diagnostics (IVDs) and related matters in the public interest;
- ensures the efficient, effective and ethical assessment and registration of medicines, medical devices and IVDs that meet defined standards of quality, safety, efficacy and performance; and
- ensures that the process of assessing and registering medicines, medical devices and IVDs is transparent, fair, objective and concluded timeously.

Enormous costs are incurred in IP development and the generation and collation of information relating to safety and efficacy through a series of studies in the required format.(3)

It is therefore essential that companies have broad and secure IP rights, most importantly in the form of patents allowing them to make and sell products and ensuring that information, processes and formulae are kept confidential. Together with regulatory approvals, these factors are a company's tradeable assets.

Key considerations in this regard include:

- What products and technologies fall within the scope of the IP rights held by the company? Do the company's IP rights cover its core business? As the Australian Institute of Company Directors Guide for Life Science Company Directors states, "a patent portfolio that looks impressive on paper may not in fact protect a particular product of the company, either because the patents do not cover the product, or do not cover an easily available workaround".**(4)**
- Does the company own or control these IP rights?
- What is the status of these IP rights? Have they proceeded to grant of registration and are there any impediments to their continuing validity?
- What is the duration of patent rights that have already been granted?
- How has the company managed its IP rights? Have effective systems been implemented to identify, record, use, value, protect and exploit IP rights? For example:
    - Is a patent register maintained and reviewed at regular intervals?
    - Have the IP rights been managed so as to realise value (eg, through further regulatory clinical trials, identifying alternative uses or indications, licensing, understanding the product life cycle, market, potential, competitors, legal protections and insurance)?**(5)**
    - Have partnering or collaboration contracts been comprehensively and clearly drafted and managed?
- Where will the company obtain the initial regulatory approval for its product and in which jurisdictions is regulatory approval sought, and in what priority?
- What stage of development has the product reached in terms of regulatory approval? How long will it take to reach the next key developmental milestone and what is the likelihood of regulatory approval? (The outcome of clinical trials, the date of submissions to various regulators and the grant of marketing authorisation of the product are typical triggers for deferred payment pricing mechanisms. Currently, regulatory delays and disruption to clinical trials, occasioned by COVID-19 should be taken into account.)
- Is the technology competitive? Once patents expire, if information relating to safety and efficacy is freely available, a third-party product can be substituted and profit from the information.**(6)** Does the technology have a defined market?

Large, growing and preferably international market

By way of example, Disa Vascular, a stent manufacturer and one of Bioventures' investees, received EU regulatory approval which made international markets more accessible.

A further key consideration is whether funding is available to break into multiple markets by attending trade shows, undertaking marketing and following up on leads and enforcing contractual arrangements.**(7)** The restriction of marketing activities occasioned by COVID-19 should also be considered.

Multiple products and markets rather than a single product and market

The rationale for this preference is to diversify risk.

Key considerations in this regard include:

- Does the company have a portfolio of products or markets?
- Are any of the products already licensed to or subject to partnering or collaboration arrangements with third parties?
- So-called 'jointly held' IP rights can create deadlock if the parties cannot agree on the manner of exploitation.

Quality and balanced management team

A quality and balanced managed team is essential at the time of negotiating a transaction and going forward, either in the form of board representation or in the form of performing transitional services for a defined period following the implementation of the transaction.

Key considerations in this regard include:

- Does the management team have a history of commercialisation and a diversity of skills? For example, skills that are scientific and technical, clinical, strategy, legal and regulatory, finance or accounting and reimbursement in nature.
- Is the management team aligned with the buyer's objectives? Specifically, the following should be observed:
    - Before negotiating the transaction, any governance issues should be resolved and sufficient operational resources should be dedicated to information assembly,

investigation and presentation to ensure the smooth flow of information without unwanted surprises for the buyer's diligence. Kinks should be identified by the company and ironed out in advance of the buyer's diligence check.

- Prolonged discussions on valuation should be avoided, projections should be reasonable and earn out or other deferred pricing mechanisms linked to milestone achievements can bridge the price expectation gap.
- A memorandum of understanding or letter of intent and a term sheet will reveal whether the company and its management team are sufficiently aligned with the buyer. The purpose of a memorandum of understanding is to "outline the contours of [the] deal" and it should focus on only the major terms of consequence**(8)** such as price, structure, price adjustments, representations and warranties and closing conditions. The deal contour is typically non-binding as it is subject to further analysis and negotiation. Confidentiality and buyer exclusivity provisions (whereby the seller undertakes not to sell or solicit other buyers for a limited period) are typically binding.

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Endnotes

(1) "6 Private equity predictions for 2020". Available here.

(2) Further details are available here.

(3) Australian Institute of Company Directors, *Guide for Life Science Company Directors* (1st ed) (2005) p 9.

(4) *Ibid* note 3, p 32.

(5) *Ibid* note 2.

(6) Joseph K. Andonian, *A Short History of Licensing in the United States*", (2016) 1 Les Nouvelles 35.

(7) Masum and Singer, "Venture capital on a shoestring: Bioventures' pioneering life sciences fund in South Africa", BMC International Health and Human Rights 2010, 10 (Suppl 1): S8 p 8.

(8) Brian P O'Shaughnessy, *Devising More Durable Deals – Avoiding Common Pitfalls in Patent Licensing*, (2018) 1 Les Nouvelles 24.
