

# New Realities, Challenges In Biotech

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**Market for new bio and pharma products growing; aging dependent population offers huge opportunity**

**L**ike many companies, Drug Royalty's business in health care innovation. The difference is that while the companies' innovative springs come from research and development and from the science underlying their products and technology, ours derives from a detailed understanding of the biotech-pharma industry and of the unique expertise and ideas we can provide to help finance late stage biotech-pharma initiatives.

At the end of the day, companies thrive by bringing to market technologies and products that enable people to live healthier, longer lives. Our contribution to the process involves combining the understanding of what companies do with our knowledge of and connections with international capital markets to help advance and accelerate the process.

I shall discuss the current state of capital markets and what this implies for biotech companies. I will then follow with a discussion of how my company is building its business and of how companies can access and take advantage of what we can offer. I will conclude by sharing Drug Royalty's view of the future for Canada's biotechnology industry.

Successful business is founded on three financial building blocks—liquidity, the cost of capital, and income expectations. Liquidity gives the freedom to operate independently of month-to-month cash problems. Assured sources of low-cost capital make it possible to raise and deploy the most promising opportunities. And assured revenues are the only assurance that low-cost

capital will be available when needed.

Equity and debt are the only two types of capital available to any company. Since biotech is knowledge-based and, typically, can't offer hard assets as collateral, the option of debt financing is not open to it. Equity, or common share financing, is the only real option.

The biotech business is risky. Some 5,000 to 800 compounds must be evaluated to develop just one new drug. And this process gets longer by the decade. It averaged eight years in the 1960s, over 11 years in the 1970s, 14 years in the 1980s, and 15 years in the 1990s. While the regulatory approval stage of the process has increased constant over this period, the time to get through the pre-clinical and clinical phases has doubled and tripled, respectively. Little wonder that bankers aren't interested.

Initially, the biotechnology and pharmaceutical industries in North America and particularly in the U.K., which I'll refer to as Europe, has not really needed or wanted traditional bank financing in the 1980s. The past five years have been unprecedented. The period has seen enormous amounts of liquidity, billions of dollars of public and private capital, invested in pharmaceutical discovery and development. Over 180 IPOs have occurred, most of them in North America.

One of the outcomes of this massive investment is that the pipeline is full of products. One thousand new molecules are being developed by pharmaceutical companies in the United States alone. Some 200 biotechnology products have reached the clinical phase of approval. The biotechnology industry is really debanking on the promise to improve both the quality and length

of people's lives. The advances include innovative cardiovascular therapies, drugs to combat HIV/AIDS, and cures for very simple cancers, not to mention lower cost, more-effective treatments for diabetes, and for neurological and respiratory diseases.

The process is not only capital-intensive, it has also been diffused—scattered across a wide range of therapeutic categories and involving more than 2,000 companies in dozens of locations worldwide. In Canada alone we have almost 100 biotechnology companies operating in many different therapeutic areas, with many different technology platforms, and at many different stages of development.

This diffusion has adversely affected the commercialization of many of these promising drug-and-technology, especially over the last three or four years. As a consequence, investors have not received the returns they expected, and their confidence in the industry has been shaken dramatically. The result is that equity capital is no longer in action for early- and mid-stage biotech developers, despite the fact the world is awash in capital.

## • Bridging Gap •

The issue now is how to bridge the gap between the potential of the science and the expectations of investors. Let me provide a recipe. First, biotech firms at the pre-clinical or the development-discovery stage, up to and including phase one, must expand the number of sources they look to for

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equity investment) to include high-net-worth "angels," venture capitalists, and pharmaceutical partners and academic sponsors. They can forget the IPO route, of course, unless they already have a strong and reliable cash flow to sustain them. The probability of success at this stage is 10% at best, and the time to market and revenue generation is at least five years. A simple one-dollar invested at this stage must generate \$20 in seven years, just to match the returns the investor would receive in the same period by investing in an index of stocks on the New York, Toronto or London Stock exchanges.

Firms at the mid-stage of clinical development have at least three options to choose from in their search for capital. Venture capitalists, again, play a major role here, especially those who can provide strategic direction and leadership at the board level as well as access to other sources of capital. The mid-stage is the right time to find a global pharmaceutical partner to not only help finance clinical testing and approvals, but to help design the clinical tests so that they are completed properly.

If a global pharmaceutical partner is not available, a CRO, a clinical research organization, not only has the expertise to help design and complete clinical studies, but can often provide value-added services including financing for product development.

Firms at the later stages of development, or with products already in market, have reached the point where risk is lower and the probability of success much higher. They should look to global pharmaceutical partners who can help launch the product or technology globally and who can finance it through the final stages of clinical approval.

Later-stage development is the time to look to the IPO or the public equity markets. Injections of public equity reward the venture capitalists who have supported the venture for years and who have raised their equities by bringing other partners into the deal. It also pays out the private investors who have stuck with the development through

the difficult, high-risk early- and mid-stages.

#### ◀ Seeking Partners ▶

This is also the time for the board and management to begin looking for partners. Is an alliance appropriate and possible? Is it the time to merge or to be acquired by a group of companies that can bring the new products and technologies to market faster and better?

This also is the stage at which organizations like Drug Royalty can help. We can bring substantial amounts of capital to firms that have completed most of the phase-three clinicals, and are now within a year, perhaps 18 months, of launching their products.

Generating revenues by licensing products and technologies to other parties is a common practice in the biotech and pharmaceutical industries. Royalty revenues generated this way typically come in over the period of the licensing agreement.

Royalty financing enables a company to finance all or a portion of a royalty revenue stream immediately. A royalty-based capital injection can be used to finance the final stage of the product development process without affecting the equity structure of the company. It does not dilute ownership and may protect IP's. This can be a very important piece to company planning in initial public offerings. Since royalty financing doesn't involve ownership, it allows the recipient company to retain full control of its intellectual property and other assets. This can be extremely important in view of the time and money needed to develop these assets in the first place. Why give them away at such a late stage in the development process?

Equally important, although the risk is substantially lower at this stage, getting through the final stages of clinicals, and obtaining the necessary approvals in different countries, as well as launching a new product, are not exactly risk-free activities. A royalty financing deal helps mitigate these risks by providing capital that is secured by future revenues.

Drug Royalty Corporation has

developed a three-pronged business strategy that was launched in 1988. First, we will provide capital to our partners or clients today in exchange for a share of royalties they are generating or will generate from sales.

To give you an idea of how big this market is, the global pharmaceutical industry, in which biotechnology plays an important part, had sales last year of 1,983,000 billion. Over 450 billion of that amount was spent on product development including discovery, completing clinicals, and the regulatory approvals. What is less well known is that more than \$40 billion of the \$388 billion is in the form of royalty revenues generated through licensing agreements to basic biotech. The capital-generating potential of this royalty stream is virtually untapped and represents a huge business opportunity for us.

The second component of the strategy calls for us to acquire, outright, royalty streams from academic and other sources in order to broaden our revenue stream.

The third part of the strategy involves direct investment of small amounts of capital in proprietary technology that offers exponential possible value to our shareholders.

To date, we have made almost \$90 million of investments in pharmaceutical and biotechnology industries around the world. The investments are focused in the United States, Canada and the U.K.

We have pursued partnerships with financial institutions and pharmaceutical companies around the globe, and have amassed a huge amount of knowledge about the biotech/pharma industry and its products and technologies. We plan to increase the size of our portfolio of investments to \$200 million. We expect our investments to generate in excess of \$20 million in sustainable revenues annually.

In the process, we will have built a high-growth portfolio that includes big pharma development products, and newly acquired biotechnology and pharmaceutical royalties. Our list of partners and clients will also include universities with whom we plan to reach unique agreements that allow them to

capitalism on intellectual property that offers high commercial potential.

The past five years have been unprecedented in terms of liquidity and the willingness of equity investors to back pharmaceutical developments. That era is over. Despite the influx of equity during this period and the optimism accompanying it, the outcome for public and private investors in biotechnology firms has been largely disappointing. Investor expectations have not been met. The result is that the confidence of financial markets in the ability of early- and mid-phase biotechnology firms to generate acceptable returns in a reasonable period has evaporated.

Of the 100 or so private biotech

companies in Canada, 90% would be classified as early- to mid-phase. These companies can no longer look to public equity markets for support because they are seen to be too small and at too early a stage of clinical development. The situation for biotech firms in Canada mirrors the situation worldwide. In many respects it's a return to basics. Equity investors have adopted a show-me-the-money attitude, and are confining their interest in biotech-pharma to later-phase opportunities where the chances for success and returns are much better.

Early- and mid-phase companies must adjust to this new reality. As I indicated earlier, they need to develop a number of sources of

capital including venture capitalists, angels, global marketing partners, and clinical research organizations. They must also concentrate on getting through the clinical development phase much more quickly in order to reach market sooner and to generate the returns investors are expecting earlier.

The market for new biotechnology and pharmaceutical products and therapies is as big as it ever has been, and it is growing. An aging population worldwide has an expectation of a lifestyle that will be much better than the one their parents enjoyed. This presents a huge opportunity for everyone in this industry, provided we can develop new approaches to financing our ideas.