

# From Molecule to Market Series

## Part I: Finding the Money

### Introduction

This is the first article in our "From Molecule to Market" series, where we address the different phases in the animal health product development journey.

Each step has its challenges and could potentially jeopardize all the work done to reach that point. Due to the complexity and vastness of the topic, we'll dedicate an article series in order to take a deep dive into the intricacies of the drug development process and what it takes to get an animal health product to market.

In this article, we share our insights on funding your idea.

### Finding the Money

The age-old problem how to find the funding to support a project. Whether you are a start-up with a great idea or a large multinational, there are always too many ideas or projects to support. This paper will endeavor to outline some of the (possibly more novel) options available to fund animal health developments.

Regardless of the size of your organisation or business, to secure funding it is important to clearly articulate:

1. Why the project is worth investing in.
2. What the potential financial reward on completion is.
3. How the risk profile and the chances of success look.
4. The road map for the project, including timeframe and budgets.

### Types of Funding for your Idea

There are a number of ways to fund your business or project:

- Your own money.
- Government grants.
- Equity funding where an investor will take a stake in your business.
- Incubators.
- Borrowing money.
- Product financing.
- Partnering with a larger player, which is more applicable to smaller start-up organisations.

it will depend greatly on the circumstances, which is appropriate, and often a combination of a few sources will ultimately be the outcome.

### Government Grants

These come in various forms and differ by country/state, it is worth investigating what is available and understand the nuances as it may inform some of the decisions you make, such as where development work is done.

Several governments offer R&D taxation incentives, where money spent on development and research can have tax benefits. Expert tax advice can be useful to ensure you are aware of what's available.

In areas where the Government has a special interest, for example ruminants and their effect on climate change, they

## Funding Options



may offer grants to support development of products that can support their efforts in a particular area.

Governments sometimes have grants available for new businesses, or a business that has the potential to benefit the country or state economically, such as employing people.

Typically, Government grants will pay a percentage of your investment, so you will still need to find other funds.

### Equity Funding

With equity funding you bring funds in by selling part of your company to investors, known as equity capital. This dilutes your overall shareholding, but often having a smaller share of something bigger is better than a large share of something small. Large multinationals will often raise funds through a capital raise to fund an acquisition or a major expansion. Smaller businesses bring in investors such as angel investors, venture capitalists or private equity. Angel investors are often successful entrepreneurs and bring in early money to an organisation. Given the risk profile of a start-up, they will be wanting a high return on the money invested. Venture capitalists invest in higher risk early-stage businesses and are also looking for higher returns. Private equity tends to invest once a company has been operational for a number of years and has a successful track record. They invest as they see the potential to grow the business, possibly through additional investment and through acquiring a number of similar businesses to create a larger company. Private Equity usually has an investment window of 4 to 8 years depending upon the type of business, after which they sell to liquidate the return on the initial investment.

Investors are buying into a business when they believe in the people and the project, and are seeing potential financial rewards in the medium term. The type of investor will depend on the stage the business is in. The higher the risk, the higher the return the investor wants.

The advantages of bringing on investors is that they bring additional knowledge and skills which can support the development of the product and may expedite the project. Alternatively, diluting the shareholding and decision-making rights may not be attractive to some founders.

### Incubators Specializing in Animal Health

There are specialist incubators within the Animal Health sector looking for new, innovative solutions, usually early in the development process. These incubators assist with sourcing funding, management, and strategy development. In return, they will take an equity position within the company. They can bring an established network that can act as advisors. The equity position that the incubator takes will dilute the founder's shareholding. However, this dilution needs to be balanced with the benefits a specialist incubator can bring to expedite the development.

### Borrowing Money

Money is usually borrowed from a bank or financial institution. The advantage is that there is no dilution to the ownership of the business. Though for a start-up, a financial institution may want additional security to protect themselves in a default situation. Typically, a financial institution will want to see a business plan, financial reporting and forecasted profits, and understand where the money is to be invested. The higher the risk the higher the interest rate.

### Product Financing

This is a more novel approach to funding the development of an animal health product. There are funds specialising in investing in pharmaceutical products and – more recently – specifically in animal health assets. They understand the risks and timelines associated with the product development journey of a new product.

The advantages of this type of funding are that it's specific to the product and doesn't dilute the shareholding

in the organisation. Large or small organisations needing funds to develop a product can look to this approach. The risk of the development is shared between the fund and the business. How the risk is shared between the parties will determine how the rewards are shared at the end of the development. The funds' way to make a profit is through the sale of the developed/registered product. The cleaner and simpler this sale process is, the more attractive the proposition. The fund is unlikely to be interested in a drawn-out payment schedule based on sales performance.

To expand on this financing method, let's talk through a hypothetical example. A start-up has a potential vaccine and initial early-stage studies have indicated it may offer therapeutic benefit to prevent facial eczema in sheep. To fully develop this vaccine and achieve registration in the US, it will cost an estimated USD\$20m and take 7 years. A fund specialising in pharmaceutical development may be interested in investing in this development with the intention of selling the registered vaccine on successful registration. The return the fund requires from this sale will depend on the risk profile of the project. Before investing in the product, the fund will do significant due diligence, considering

- the market potential of the vaccine
- other treatments already on – or coming to – the market
- who is doing the development and if they have a successful track record
- the probability of technical success (pTS)
- the studies done to de-risk the project especially in the early stages
- required patent searches to confirm freedom to operate
- which companies would be interested in buying the vaccine to market on successful registration
- the cost effectiveness for the end user

A specialist pharmaceutical fund may take on some of the development risk. So, if the product development fails, the money may not need to be repaid. This risk/reward scenario means that the fund will want a significant share of the reward if the product is successful.

The fund needs to have confidence in the company that is doing the product development, clinical studies, and regulatory work. They will be looking for significant experience and a successful track record, including managing budgets and timelines. Prior to approaching a fund, having a detailed plan around the development and who is doing the work will support the discussion with the fund. If the work is being done in house, also provide examples and case studies of previous development projects and the credentials of the people working on the project. If being done by external parties, select well known, experienced partners that the fund will have confidence in to deliver the desired outcome.

### Partnering with a Large Animal Health Company

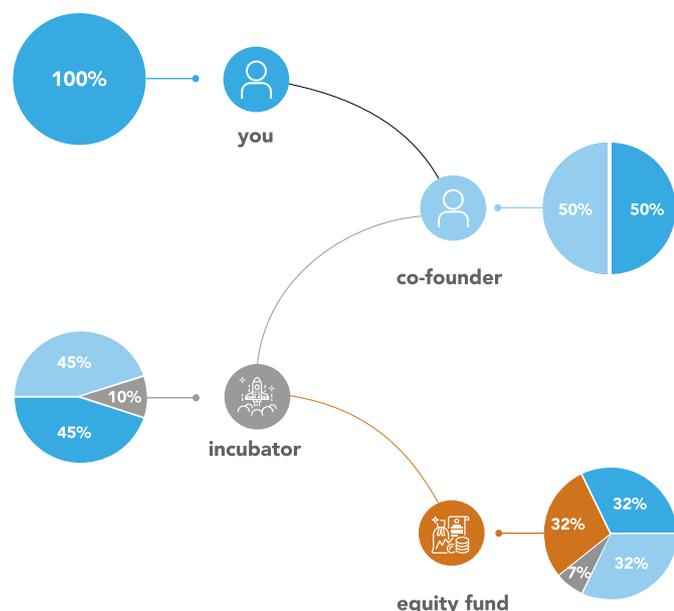
Large companies are always looking for new and interesting therapeutic opportunities. Approaching one may present different options to extract value from your asset. There are several options:

- the company may be interested in licensing and taking on the full development where the start-up would receive royalty payments if the product was successful
- they may want to buy the asset outright
- they could support with some funding to determine viability.

The partner, as with a product financing fund, will want to do due diligence and will ask similar questions to those above.

## Shareholding Dilution

EXAMPLE



The discussion to date has been around funding a product through to registration. However, there are other ways for a business to extract value from an asset, without necessarily having to do the full development. It may be worth considering other options if a business has a number of opportunities liquidating one asset that may help fund some of the other opportunities. Liquidating an asset could be an outright sale based on some initial data, demonstrating strong indications. Alternatively, a license deal that has some upfront payment and then a royalty stream is another option. In these scenarios having good Intellectual Property protection is necessary.

### About Argenta

Founded in 2006 in New Zealand, Argenta holds a unique position as the only combined global contract research organisation (CRO) and contract development and manufacturing organisation (CDMO) dedicated to animal health. Argenta's talented and committed employees are dedicated to deliver excellence in animal health to customers around the world. With research and GMP manufacturing operations in the United States, New Zealand, the United Kingdom and Germany, Argenta operates from 'Molecule to Market' in partnership with customers of all sizes from all corners of the world, to seamlessly support their research & development, clinical research, regulatory, scale up and manufacturing needs along their veterinary product development journey.

Recently, Argenta has taken a pro-active approach in accelerating new product development opportunities. There are instances where this journey is fully funded by the client or, in other scenarios, Argenta can help source funding to support the development. The sweet spot is molecules that have a strong initial data package indicating a greater than 40% probability that the product will successfully achieve registration.

### How it Works

When Argenta is approached by a company looking for a partner to develop their product, Argenta does an initial due

diligence after signing an NDA (Non-Disclosure Agreement). This is a screening exercise to ensure that Argenta can add value. If this is the case, a much more detailed review is undertaken.

Part of this is a commercial discussion on how the parties can work together and if external funding is required. After this, a number of work streams start, including developing a detailed Product Development Plan along with estimated costs and commercial arrangements. Once the product development starts, there will be regular governance meetings to keep the parties updated on progress and to make key decisions as the project passes through the various gates towards the goal of successful registration.

For more information, visit [www.argentaglobal.com](http://www.argentaglobal.com).

Stay tuned for new articles in the "From Molecule to Market" series:

- Part I: Finding the Money (this article).
- Part II: Start with the end in mind – Formulation, drug delivery technology, and manufacturing.
- Part III: Is it Safe & Effective? Clinical Studies, Data Management and Quality Assurance.
- Part IV: Getting your product approved – Regulatory considerations for the EU and US.



### Darrell Morgan

A Biologist from Wales in the UK, Darrell started his career in immunodiagnostics for Amersham International before moving to "big pharma" in human health, where his career included developing sterile ophthalmic products, Metered Dose Inhalers, Zavesca® a NCE for rare developmental diseases in children and sterile large molecules for inflammatory conditions (Cimzia®). Darrell went on to gain post-graduate qualifications in management, people and change as well as Industrial Pharmaceutical Sciences before joining a Belgian biopharmaceutical company (UCB) in 2004. Darrell relocated to New Zealand in 2012 to join Argenta where he led Pharmaceutical Sciences. During his tenure leading Pharmaceutical Sciences, Darrell led the development of multiple animal health products including Galliprant, and two other products for Aratana, plus a range of products for the Asia Pac region. More recently he has led the start-up of Argenta's new Product Development organization, leading all technical aspects of Product Development. Darrell lives rurally with his family near Auckland, and has a small flock of sheep, ducks, and two rescued rabbits!



### Clare Morgan

A career spanning 30 years in commercial roles, predominately in consumer goods. Clare has a wealth of commercial global experience, recently returning home to New Zealand, after living in Singapore responsible for launching a range of nutritional based beverages throughout South East Asia. Clare has been working with Argenta for over 18 months, supporting Argenta's new Product Development organisation, leading the commercial aspects of Product Development.

Healthy Animals.  
Let's Make It  
Happen, Together.

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