# PCP13: Impact of outcome-based annuities on small biotech companies

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## Introduction

With an increasing number of biotech companies developing potentially curative treatments (Fig 1), both drug manufacturers and payers face challenges of funding and reimbursement. One potential solution – proposed in markets such as the UK – is to devise creative and innovative payment strategies, such as annuity payments tied to performance (Fig 2).

Under the performance-based annuity payment model, payers would pay for one-off treatments in instalments (e.g., yearly, monthly) over the lifetime of the patient. This allows payers to spread cost over multiple time periods and ensure healthcare systems only pay for the working life of a treatment.

In this study we will explore the feasibility, opportunity and challenges such a payment system entails for small biotech enterprises, such as those which have only one asset. We aim to answer fundamental questions on how annuity payments impact the healthcare system, given high cost of goods associated with gene/cell therapies and payment risks involved. In addition, we will also look into the impact of annuity payments on the financials of the biotech, and the price and value of the product when adjusted for the cost of credit.

## Methodology

Qualitative information has been collected through in-depth interviews with various commercial experts across academia, and the biotech and finance industries. Respondents were interviewed from university institutions, business schools, private equity groups and small biotech.

These insights were leveraged together with CRA's internal expertise. GlobalData was used to obtain launch dates and regulatory details on existing gene therapies. Cell and Gene Therapy Catapult together with open source news articles were used to gain deeper insights based on breaking developments in the industry.

## Discussion and conclusions

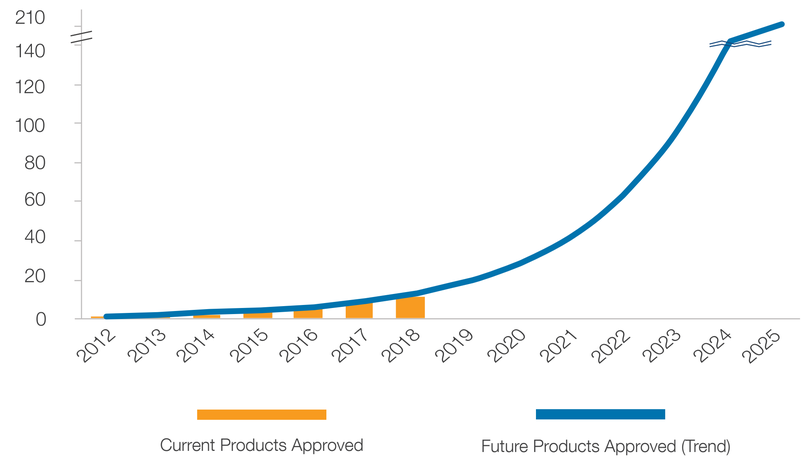
For payers, performance-based annuity payments can address an affordability problem for potentially curative therapies and reduce uncertainty around clinical value. However, this could create a negative impact on a biotech from both a value and cash flow perspective. Value could be negatively impacted if there is risk associated with the annuity payment – both guarantor risk from the payer guaranteeing the contract, and valuation risk from the requirement for a time value of money calculation.

At the same time, using government or health-insurer backed annuities as collateral for secured loans, smaller biotech companies could mitigate negative cash flow effects through secondary markets. However, there needs to be a careful consideration of the impact of the cost of credit set against any operational repayment milestones and expected cost of goods post launch (Fig 3).

The source of the loan is most likely to come from the biotech's bank, although a boutique private equity group could also be a source through equity/debt financing. Using the contract as collateral, the duration of the contract and level of commitment from the payer are key determinants for the cost of credit. If annuity payments are performance-based, then rates would increase due to the introduction of variable risk per patient. A detailed overview of all the other requirements that the biotech would need to meet are illustrated in Figure 4. The interest rates of these loans would have a negative impact on the value of the biotech.

Implementing these strategies successfully can create significant capacity strain, especially for a smaller biotech. Such firms should now consider a broader set of stakeholders for reimbursement, including finance providers (e.g., banks or private equity groups), and specialist life science consultants for expanded pricing and market access research and strategic due diligence.

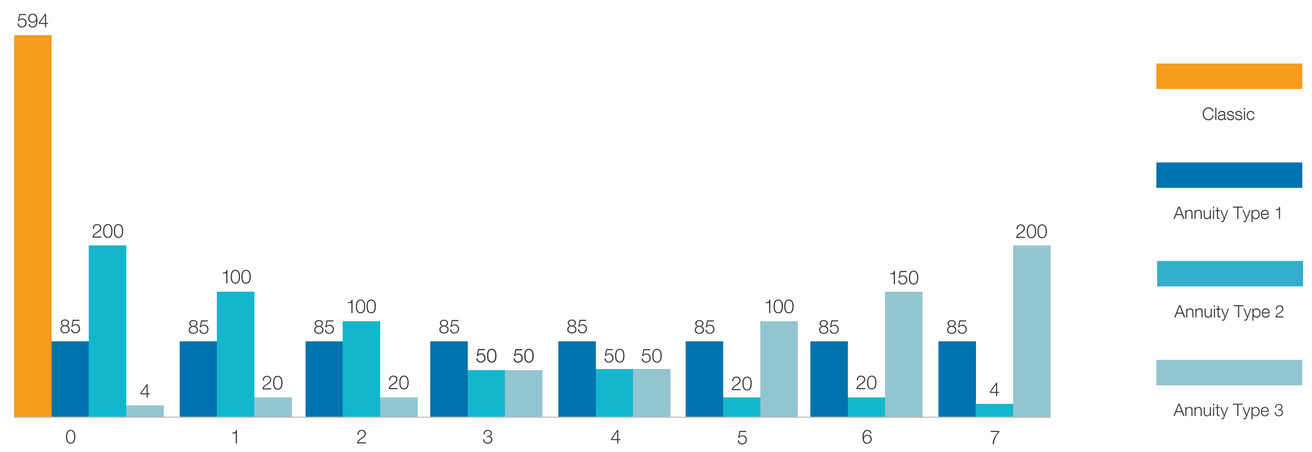
### Figure 1: Approved ATMP 2012–2025 (extrapolated)




Gene therapy launches are on the rise. With cost per curative treatment expected to be very high (~EUR1M), payers are reluctant to pay such cost upfront due to inherent uncertainties in treatment outcome for each patient. With 34 gene therapy drugs currently in pivotal trials, the situation is likely to worsen in future. This figure illustrates a simple extrapolation of the current trend.

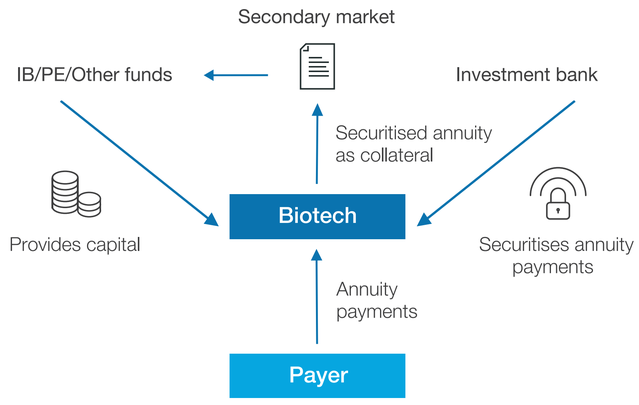
In order to avoid high upfront costs, payers have started investigating reimbursing treatments in installments or annuities. Annuity payments address payer concerns on uncertainty and budget impact, and could be an answer for gene therapies with large patient populations and high upfront cost.

### Figure 2: Annuity payments as a reimbursement solution for payers




Strimvelis is reimbursed only in one Italian centre, at €594,000 through a money-back guarantee agreement made by GSK. Internal factors affecting payment schedules could relate to company size or product type. For instance, smaller companies are more sensitive to longer-term payment schedules – due to the high expected COGS associated with curative treatments. External factors include the market (discussed in Figure 3) and the patient population.

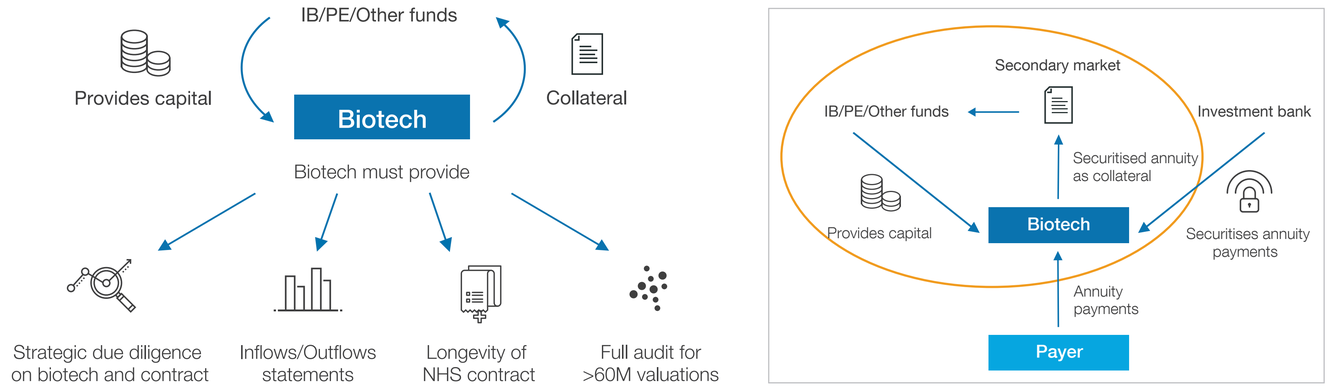
### Figure 3: Implications that annuity payments will have on the biotech




The biotech needs to have a secure and predictable cash flow for future operation financing. The most viable solution for the biotech in this situation is to offer the annuity payments on a secondary market in exchange for a loan – using the annuity as collateral, the biotech can establish a credit line to eliminate adverse cash flow effects.

The biotech has to consider the cost of capital in addition to any inflationary effects that might affect the value of future payments. This is highly market dependent, and involves the biotech engaging in complex financial negotiation or valuation – potentially a significant capacity strain on small-scale organisations.

### Figure 4: Impact of annuity payments on biotech financing and value




In order to establish a credit line that will mitigate any negative cash effects, the biotech will most likely interact with a bank. Interested boutique private equity groups could also be a source of equity or debt financing.

In either case the biotech will have to provide audited statements on all of its inflows and outflows. Financial a due diligence of the contract would be done by the bank in addition to a strategic due diligence to asses payer interest. If the annuity payments are outcomes-based then the loan would be priced with a variable risk, but in general the rates would go up in this case.

**References**

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