Marketspace

The DNA/RNA market to 2010

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Abstract

The DNA/RNA market is currently at an early stage of development, with only two marketed products that together generated an estimated US$30m in 2004. The launch of Pfizer/Eyetech's ophthalmological aptamer Macugen (pegaptanib) is set to help power market growth to US$1.2bn by 2010. Of the 229 active DNA/RNA programmes identified by Datamonitor, oncology currently dominates the therapeutic focus, while antisense and gene therapies dominate the technological focus.

INTRODUCTION

The DNA/RNA market encompasses antisense oligonucleotide therapies, gene therapies, RNAi (RNA interference), aptamers (including both Spiegelmer and non-Spiegelmer aptamers) and ribozymes. Companies developing products based on DNA/RNA technologies are post-genomic companies whose products and platform technologies provide the most direct route to commercialising the human genome. However, the DNA/RNA market is still at an early stage of evolution, and generates the smallest sales of all major biotechnology sectors (including recombinant proteins, monoclonal antibodies and vaccines). Within the DNA/RNA market, the different technologies are at different stages of maturity, with antisense and gene therapies representing the most mature and intensely studied technologies, while technologies such as RNAi are recent scientific developments that are acting to reinvigorate interest in the DNA/RNA market.

The future performance of the DNA/RNA market is dependent on the successful development and launch of a series of DNA/RNA products representing a range of technologies, including gene, antisense and aptamer therapies. The launch of these key products will be a dominant factor in determining the development of the sector and influencing investor behaviour. Therefore, Datamonitor's biotechnology analysis has focused on characterising active DNA/RNA product-development programmes and then identifying and analysing products set to be on the market by 2010. These products are then analysed by therapeutic and technological focus to create a market forecast through to 2010. This analysis methodology is represented in Figure 1.

DNA/RNA MARKET ANALYSIS AND KEY MARKET DRIVERS

Datamonitor global research has identified 229 active DNA/RNA product development programmes run by 99 companies. Of these products, 19 are forecast to have reached the market by 2010. Using a risk-adjusted market forecast, the successful launch of these products will drive market growth from an estimated US$30m in 2004 to US$1.2bn in 2010 (Figure 2). This forecasting methodology weighs up the strength of each product, based on

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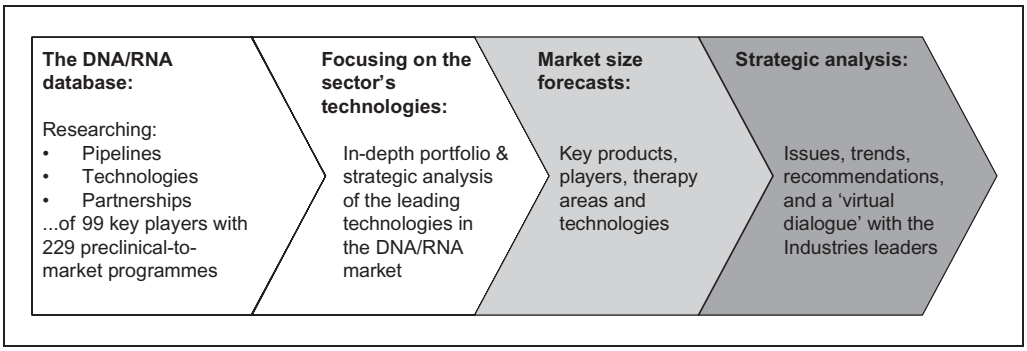

Figure 1: The structure of Datamonitor's analysis methodology for analysing the DNA/RNA market
Source: Datamonitor

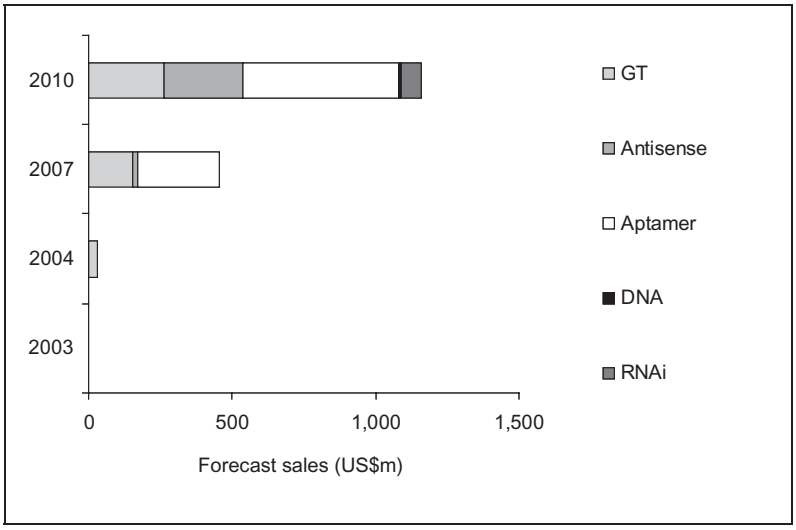

Figure 2: Risk-adjusted total DNA/RNA market forecast, to 2010 (GT, gene therapy)
Source: Datamonitor

innovation (the drug's potential) and business development (the commercial viability of the drug), and, when amalgamated, creates the total risk-adjusted market forecast.

Sales of Eyetech/Pfizer's ophthalmological aptamer Macugen (pegaptanib) represent all sales likely to be generated by aptamers over the forecast period, with Macugen sales forecast to generate 45 per cent of the total market sales by 2010. The product's forecast success is due to its optimal business development (through its 2002 development and commercialisation collaboration with Pfizer) and innovation (strong Phase II/III data, in terms of efficacy and side-effect data) profile.

TECHNOLOGICAL AND THERAPEUTIC FOCUS OF THE DNA/RNA MARKET

Mostly driven by Macugen's critical contribution to market growth, the DNA/RNA market is skewed towards an ophthalmological therapeutic focus and the aptamer technology platform, in terms of sales. However, when quantifying the numbers of product-development programmes, there is a very broad range of therapeutic foci and technology platform diversity.

In terms of the numbers of active product-development programmes, oncology represents the dominant therapeutic focus for active DNA/RNA programmes identified by Datamonitor, accounting for 96 programmes, or just over 40 per cent of all programmes (Figure 3). This trend is replicated through preclinical and clinical trial development, with the greatest proportion of oncology programmes in early clinical development.

After oncology, core therapy areas targeted by pharmaceutical and biotech companies also generate significant interest in the DNA/RNA market, with central nervous system (CNS) and cardiovascular representing the two next most popular therapy areas after oncology. Genetic disorders account for a proportionally larger percentage of active DNA/RNA programmes, compared with the total pharmaceutical/biotech market, which is due primarily to the suitability of gene therapy (GT) for treating such indications.

Significant funding has been pumped

into gene therapy development and this technology platform is considered to be the most actively studied DNA/RNA technology (Figure 4). However, no DNA/RNA company has successfully brought a gene therapy to the market in the USA or Europe. Conversely, although there are fewer antisense product-development programmes, the greatest proportion of late clinical/launched DNA/RNA products are antisense products. This indicates that antisense technology has begun to harness the wealth of preclinical and clinical trial data as it moves along the path of bringing efficacious and safe products to the market. Newer technologies such as RNAi have reinvigorated interest in the DNA/RNA market. However, RNAi is still in its infancy and it is likely to take several years before these products strongly penetrate the market.

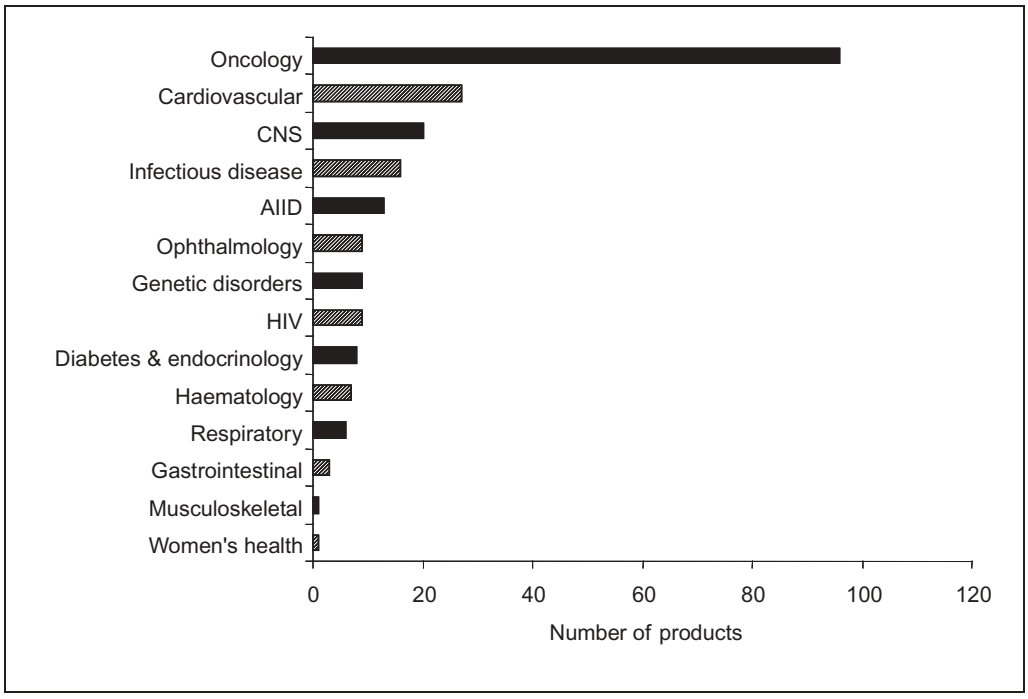

Figure 3: Total number of active DNA/RNA programmes, split by therapeutic focus (CNS, central nervous system; AIID, arthritis, inflammation and immune disorders)
Source: Datamonitor

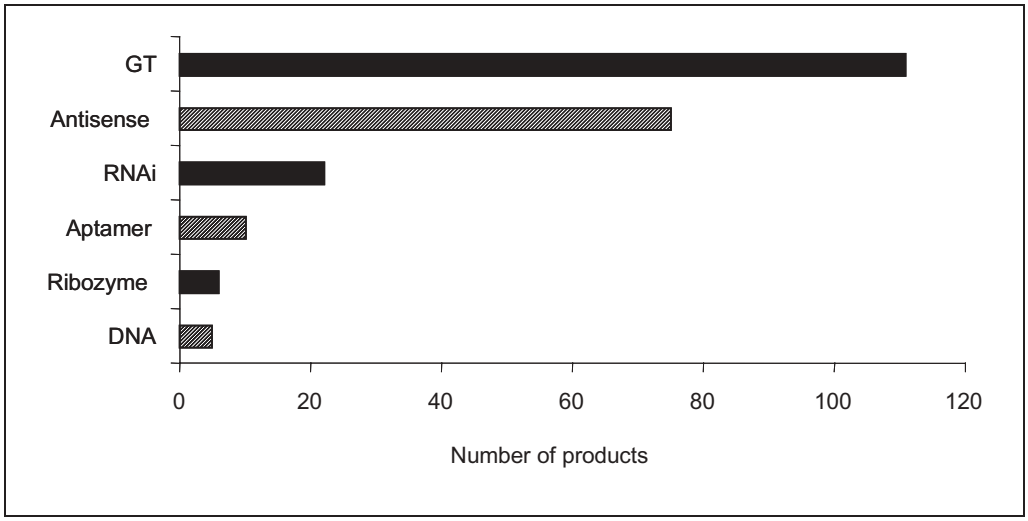

Figure 4: Total number of active DNA/RNA programmes, split by technological focus
Source: Datamonitor

FUTURE GROWTH DRIVERS AND RESISTORS OF THE DNA/RNA MARKET

The DNA/RNA market is still at an early stage of maturity for a number of reasons, and this has retarded venture funding and biopharma investment in the market. DNA/RNA companies have to address clinical trial failures that have dogged the market, together with other factors that affect the commercial success of the products. These factors include the complex intellectual property (IP) situation, the business model strategy employed, physician training and targeting, and a range of political, ethical and social issues.

Rather than focusing towards moving to a fully integrated business model, DNA/RNA companies should aim to address these issues and demonstrate that they can deliver products through Phase III and successfully launch them into the market. The launch of both an antisense therapeutic (ISIS Pharmaceuticals's Vitravene (fomivirsen)) and a gene therapy (SiBiono's Gendicine (p53 gene therapy)), together with the recent approval of an aptamer therapeutic (Macugen) have indicated that it is possible to successfully develop and launch DNA/RNA products.

Once this has been demonstrated for a series of DNA/RNA products representing a range of technologies across the major biopharma markets (US, Europe and Japan), companies should focus on validating their pipeline through strategic alliances with leading biopharma players, to ensure strong development and commercialisation and improve their financial stability.

CONCLUSION

Analysis of the DNA/RNA market indicates that the ophthalmic aptamer Macugen is set to drive market growth through to 2010. However, 18 additional products are set to be launched by 2010, which cover a range of technologies, and these will broaden the therapeutic focus of DNA/RNA therapies. Together, these products are set to drive market growth from US$30m in 2004 to $1.2bn by 2010. However, to achieve this growth, DNA/RNA companies need to address a series of issues, including the IP situation, together with political, economic, social and ethical factors, to generate significant interest from Big Pharma and Big Biotech and secure funding and drive product development to generate revenues that will help stabilise their financial position.