
US Financial accounts reports

Glenn Crocker and Karen Smith

Celera Genomics Group (NYSE: CRA): Results for the year ended 30th June, 2001

Celera Genomics was formed in 1998 in a blaze of publicity when its founding Chief Executive, Craig Venter, announced the company would sequence the human genome within three years. The company was formed as an independent division of Perkin Elmer (now Applera Corp.) and new Applera shares were floated on the New York Stock Exchange as a separate tracking stock. These tracking (or letter) shares specifically relate to Celera, enabling Applera to split its risk profile between the higher-risk Celera and lower-risk Applied Biosystems and allowing investors to balance their own risk profile accordingly.

To achieve its goal, Celera developed one of the most extensive DNA sequencing facilities in the world and, in February 2000, the company announced the results of its efforts alongside those of the publicly funded International Human Genome project. With attention focused on the genomics revolution, Celera's shares went skyward and the company attained a valuation in excess of US\$14bn, at which point the company made the most of the high valuation to top up its cash reserves to the tune of US\$800m with a secondary offering on the NYSE.

Celera's original business model was based on the generation, sale and support of genomic information and enabling data management and analysis software, along with the provision of gene discovery, genotyping and related genomics services. As part of the Applera strategy, Celera is now expanding its business into functional

genomics, particularly proteomics and personalised health/medicine through its three business units: the On-line Information Business, Discovery Sciences and Discovery Services and through Paracel, a business Celera acquired in June 2000 that develops high-performance genomic data and text analysis systems for the pharmaceutical, biotechnology, information services and government markets.

Revenues from these activities more than doubled in the year ended 30th June, 2001, to US\$89m, from US\$43m the previous year. Research and development expenditure however, rose to a massive US\$208m (from US\$164m) as the company continued to increase its sequencing efforts and focus on the next stage in the sequencing race; development of a single nucleotide polymorphism (SNP) map of the human genome. SNPs are single base changes in the DNA that can affect an individual's susceptibility to disease or response to treatments. To develop the much-heralded 'personalised medicine' it is necessary to understand where SNPs are located and what they do. Celera intends to sequence the DNA of 40–50 individuals in an effort to unlock this information.

Although Celera's original focus has been on the generation and analysis of information, the company is keenly aware of the increasing commoditisation of genetic data. To avoid this trap, the company is moving downstream from the discovery end of the value chain into drug development. With this in mind, in June the company announced its proposed acquisition of Axys Pharmaceuticals. The deal, subject to shareholder approval, is a stock swap valued at US\$174m, the

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completion of which will provide Celera with new capabilities in the identification and validation of small molecule therapeutic candidates along with a potential drug development pipeline.

In a further effort to build capabilities in the drug development arena, the company announced in July 2001 an agreement with Isis Pharmaceuticals. Isis will use its antisense technology to provide valuable information on the function and potential medical implications of more than 200 key genes and it will contribute to the validation of potential therapeutic targets. GeneTrove, Isis's subsidiary, plans to complete the gene analysis work within 18 months. Isis will maintain the rights to develop drugs based on the genes using its technology, while Celera will have the right to select a limited number for its own drug discovery programmes. Data on the remaining genes will enter GeneTrove's database and will be sold on a subscription basis. The companies will jointly own the intellectual property generated and will share equally in any licensing. More recently Celera has done deals with the SNP Consortium and Somalogic.

The high level of R&D expenditure was compounded further by an amortisation charge of US\$44m and a special charge of US\$69m relating to the write down of the investment in Paracel. The resulting operating loss for the year amounted to US\$290m, up from US\$168m the previous year. The loss included the first expenses from Celera's equity interest in Celera Diagnostics, a joint venture established with Applera to commercialise the diagnostic uses of Celera's genetic data. Celera will fund all of the initial cash operating losses of Celera Diagnostics up to a maximum of US\$300m, after which any further operating losses would be shared equally with Applied Biosciences. Under the arrangement Celera would receive an initially larger profit share until profits equalled initial losses; at this point profits would be shared equally.

For fiscal 2002, Celera forecasts that revenue will be up between 40 and 50 per cent as it further increases subscriber

numbers but as a senior analyst at Friedman, Billings and Ramsey pointed out 'Celera's future hinges on first coming out with a diagnostic product with decent profit margins, and then some tangible evidence that they're making headway with therapeutics'. With cash reserves in excess of US\$1bn, the company is well placed to rapidly advance all three of its core areas of SNP identification, diagnostics and therapeutics.

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IDEC Pharmaceuticals Corporation (Nasdaq: IDPH): Results for the six months to 30th June, 2001

IDEC is one of the elder statesmen in this young industry, having been founded in 1986. It is also a rare beast in that it is a profitable biotechnology company; belonging to an elite club that still contains only a handful of members.

IDEC researches, develops and commercialises targeted therapies for the treatment of cancer, autoimmune and inflammatory diseases. The company's primary focus is on monoclonal antibody therapies. Monoclonal antibodies were hailed as the major medical breakthrough we had all been waiting for almost two decades ago. Unfortunately early treatments fell well short of their promise. Today, however, they are back in fashion with a vengeance. There are now an estimated 270 companies working on over 700 therapeutic antibodies, 220 of which are making their way through clinical trials. As always, there are a few companies that stand out from the crowd and IDEC Pharmaceuticals is one of them.

IDEC's first commercial product was Rituxan, a treatment for non-Hodgkin's B-cell lymphoma, which received US Food and Drug Administration (FDA) approval in November 1997. It was the first approved monoclonal antibody for the treatment of cancer in the USA and marked the

renaissance of antibody therapeutics. Rituxan is manufactured and distributed by Genentech in the USA and it was sales of Rituxan that enabled IDEC to turn in its first profit in the 1998 financial year.

Rituxan is still responsible for most of IDEC's revenues and sales are continuing to grow rapidly. Revenues for the six months ended 30th June, 2001, were US\$107m, more than double the US\$53m achieved in the same period the previous year. Overall US sales of Rituxan recorded by Genentech were US\$348m in the first six months of the year, compared with US\$174m in the first six months of 2000.

IDEC's reliance on Rituxan sales is likely to reduce, since in September 2001 the FDA's Oncologic Drugs Advisory Committee recommended approval of the company's second antibody product, Zevalin. Although also directed against non-Hodgkin's lymphoma, Zevalin differs from Rituxan in that the monoclonal antibody is conjugated to a radioisotope that destroys the cell, whereas Rituxan binds to a specific B-cell receptor that activates a killing cascade by the body's own immune system. Zevalin is expected to be used in combination with Rituxan to provide a more effective therapy. The FDA decision represents a huge win for the company although its forecasts for this new class of drug are cautious – US\$2m annual revenues expected in 2001, rising to US\$201m in 2005. This is because the company realises that time will be required to educate doctors in its use and to widen its indication.

The increase in clinical efforts related to Zevalin and a number of other pipeline products resulted in an increase in research and development costs to US\$43m, up from US\$32m the previous year. The approaching end of Zevalin's journey through the clinic was also partly responsible for a significant increase in selling, general and administrative costs, which increased from US\$13m in the first six months of 2000, to US\$23m this year.

It has not been all smooth sailing though, and in this highly litigious industry, IDEC has recently found itself

filing two lawsuits: one against Corixa, Coulter and the University of Michigan; the other against GlaxoSmithKline. The first seeks a declaration that IDEC's Zevalin product and its use in the treatment of B-cell non-Hodgkin's lymphomas do not infringe Corixa's issued US patents. The second seeks a declaration that IDEC's manufacture of Zevalin does not infringe GlaxoSmithKline's issued US patents.

The company is, however, in a strong financial position to fight its corner and to continue to develop its pipeline products with over US\$820m in cash and marketable securities at the end of June 2001. This is partly a result of the company taking advantage of the buoyant 2000 equity market to raise US\$450m in a share issue, combined with net cash inflows from operations and the income from share option exercises, as employees continue to take advantage of the rapid growth in share price the company has experienced over the past few years. The company's financial strength will enable it to participate in a greater proportion of revenues from its future products and in anticipation of this it is committed to spending US\$300–400m over the next four years developing a large-scale manufacturing facility.

The increased cash reserves also resulted in a boost in interest income, up from US\$8m to US\$22m in 2001. This contributed to an overall net income of US\$46m for the period, compared with US\$10 in the first half of 2000.

IDEC took 12 years to reach profitability. There are not many companies in the sector that have been around that long, and few look set to beat the 12 year time-scale. Bringing products to market and achieving profitable growth have enabled IDEC to rise above the pack, having hardly been affected by the general technology malaise that has afflicted global stock markets over the past year or so. With a market capitalisation of around US\$9bn IDEC has the strength to be a major consolidator in the fragmented antibody therapeutic sector. Its product profile also

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makes it an attractive acquisition candidate for one of the large pharmaceutical companies, and it is not yet so big that it would be difficult to swallow. Either way,

the company looks set to reward long-term investors for their patience.

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