April 10, 2015



Gene Techno Science Co.,Ltd. Code: 4584 (TSE Mothers) President Masanari Kawaminami

# Forecast for the Fiscal Year Ending March 31, 2016

Gene Techno Science Co.,Ltd. has released its forecast for the fiscal year ending on March 31, 2016 as follows because of the outlook for a large increase in sales resulting from strong sales of G-CSF<sup>\*1</sup> (recombinant human granulocyte colony-stimulating factor, generally known as filgrastim). G-CSF was developed by Gene Techno Science and Fuji Pharma Co., Ltd. Sales began on May 31, 2013 as the first biosimilar based on Japanese guidelines. It is marketed by Fuji Pharma and Mochida Pharmaceutical Co., Ltd. and sales are currently strong at both companies.

\*1: G-CSF stimulates the differentiation and proliferation of neutrophils, a type of leucocyte. It also accelerate the emission of neutrophils from the bone marrow, and activates their function. Therefore, G-CSF is indicated for neutropenia, and to activate the increase of neutrophils in bone marrow transplantation patients.

	-	-			(N	fillions of yen)
	Net sales	Operating	Ordinary	Net income	Net income per	Reference:
	Net Sales	income	income	Net income	share (yen)	R&D expenses
FY3/16 Forecast	1,022 Note 2	(602)	(573)	(575)	(239.14) Note 3	739
Reference: FY3/15 Forecast Note 1	310	(970)	(946)	(948)	(397.47)	817
Reference: FY3/14 Results	301	(512)	(516)	(519)	(240.15)	412

#### 1. Forecast for the fiscal year ending March 31, 2016

Notes 1. The FY3/15 forecast is based on the most recently announced forecast, which was in the third quarter earnings announcement (*kessan tanshin*) dated February 12, 2015. There are no significant changes in these forecasts as actual results are expected to be largely in line with our plan.

2. The FY3/16 sales forecast uses a conservative outlook based on only G-CSF sales that are very likely to occur.

3. The number of shares issued increased by 12,000 on April 3, 2015 due to the exercise of stock options. The net income per share forecast incorporates this increase.

### 2. Sales forecast – Upside potential

In the fiscal year ending on March 31, 2016, we anticipate growth in sales associated with G-CSF. In addition, due to progress with several other biosimilars now under development, we are aiming for even more sales growth by receiving lump-sum contractual payments and other revenues in conjunction with alliances with pharmaceutical companies. There is a capital and business alliance with ORTHOREBIRTH CO., LTD. involving synthetic bone and we plan to use this alliance for progress involving healthcare-related businesses. At this time, it is not possible to determine reliable estimates for sales and earnings from contractual and other payments and these healthcare-related businesses. As a result, the forecast does not include sales and earnings from these sources. An announcement will be made promptly if there is a change in the outlook for these sales and earnings.

### 3. Earnings forecast - Stability of operations and faster R&D activities

In all fiscal years through the year that ended on March 31, 2015, Gene Techno Science was unable to use all of its internal financial resources for R&D expenses because earnings from the sale of G-CSF<sup>+2</sup> were less than fixed expenses<sup>\*3</sup>. This resulted in financial instability. In the fiscal year ending on March 31, 2016, earnings from the sale of G-CSF are expected to be higher than fixed expenses. Since these earnings will cover cash outflows for fixed expenses, Gene Techno Science expects to be able to use a substantial amount of internal financial resources for R&D expenses. This is significant because the company will be able to conduct R&D activities while preserving its position as a going concern. Furthermore, by using the portion of earnings that exceeds fixed expenses to fund R&D activities, Gene Techno Science believes that it will be possible to increase the speed of these activities.

In the fiscal year ending on March 31, 2016, Gene Techno Science plans to continue conducting extensive R&D activities as market conditions and its sales and earnings improve. The outlook is for R&D expenditures of 739 million yen, about the same as in the previous fiscal year. However, since part of the earnings from sales of G-CSF can be used for R&D activities, the net loss forecast is 575 million yen, which is less than projected R&D expenses.

- \*2 Earnings from the sales of G-CSF are calculated by deducting the associated cost of sales and royalties included in SG&A expenses from these sales. This is the effective earnings from these sales.
- \*3 Gene Techno Science has no manufacturing facilities of its own and most R&D expenditures are for outsourced activities (a variable expense). Consequently, fixed expenses are expenses after deducting R&D outsourcing expenses and royalties from SG&A expenses. These expenses remain the same regardless of changes in the volume of R&D activities.

# 4. G-CSF accomplishments and outlook

In recent years, there have been many activities to increase the use of generic drugs in Japan following a long period of low utilization. Furthermore, a rapid shift is taking place in the understanding of biosimilars, which are developed by using clinical trials and other programs. These events have contributed to steady growth in G-CSF sales as more large hospitals start using this biosimilar.

Gene Techno Science believes that sales of G-CSF, its first biosimilar, will grow to level that supports the company's position as a going concern. For the time being, programs to develop a second and third biosimilar will have an effect on results of operations. But the growing public awareness of biosimilars is creating more business opportunities. Gene Techno Science plans to make substantial R&D investments with the goals of enlarging its pipeline and maximizing future earnings.

## 5. Outlook

Gene Techno Science plans to use this forecast as the forecast for fiscal year ending on March 31, 2016 that is included in the earnings announcement (*kessan tanshin*) for the fiscal year that ended on March 31, 2015.

### Reference:

Gene Techno Science plans to post a message from the president on its website (<u>http://www.g-gts.com</u>) that includes a discussion of this subject (Japanese version only). Please visit the website to read this message once it has been posted.

#### Media Contact

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