

A bio-venture of regenerative medicines

Recommendation rating (Dec 10)

**SanBio Company Limited** (4592-TSE Mothers)**Overweight**

Stock Price	Unit of Investment	Market Cap	52-Week High	52-Week Low	PER (E)
1,051yen (12/10)	100Shares	46.8Bil yen (12/10)	2,117yen (15/5/13)	855yen (15/8/25)	-

**Steady progress in development of "SB623"****SanBio is braced for a clinical trial for chronic stroke in U.S.**

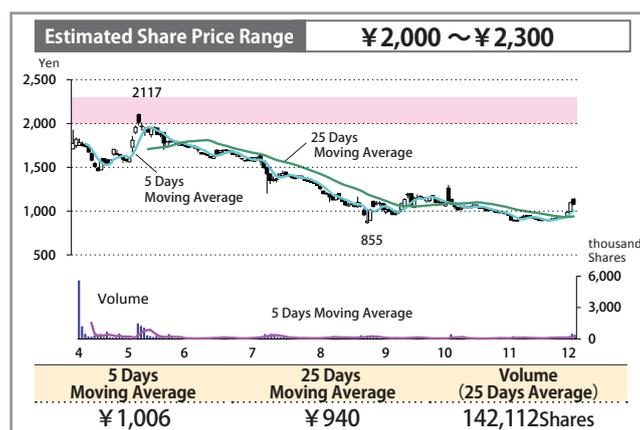
The development of "SB623", its flagship medicine among the products of SanBio's pipeline, shows steady progress. **The company is recruiting participants with chronic stroke for the Phase 2b clinical trial of the medicine to be conducted in the U.S., the principal market for its pipeline. The trial is scheduled to commence with 150 registered patients by the end of the fiscal year ending January 31, 2016 (fiscal 2015). It is estimated that the clinical trial program will take approximately 2 years to complete and we believe that the trial results will have a significant impact on the company's medium-term performance.**

With regard to the consolidated business results for the second quarter of fiscal 2015 (February 2015 ~ July 2015), SanBio posted an operating loss of 555 million Yen on operating revenue of 411 million Yen. The operating revenue included higher than expected development support funds received from Sumitomo Dainippon Pharma Co., Ltd., with which the company has entered into a joint development and license agreement. Forecast of fiscal 2015, the company expects to report consolidated operating revenue of 1,835 million Yen and operating loss of 855 million Yen. It anticipates that it will record approximately 1.2 billion Yen (\$10 million) development milestone funds and part of development support funds from Sumitomo Dainippon Pharma, in connection with the progress in Phase II clinical trial of the medicine under development. Operating expenses for the fiscal year are likely to jump to 2.69 billion Yen (compared with 0.79 billion Yen and 0.98 billion Yen in the fiscal 2013 and fiscal 2014, respectively); this largely reflects increased R&D expenses in line with the progress in various pipeline developments.

**"SB623" has the potential for wider applications, stock is undervalued**

**IPO should facilitate the development of "SB623" for wider therapeutic applications.** "SB623" is currently on clinical trial for efficacy treating chronic stroke and traumatic brain injury, but the medicine is also adapted to treat five other diseases including age-related macular degeneration, Parkinson's disease and Alzheimer's disease. Regarding these diseases, the medicine is in either R&D or preclinical phases, but its adaptability to treat a variety of diseases underlines its great advantage. On July 8, 2015, the company, announced that it was poised to begin the development of SB623 to treat patients suffering from traumatic brain injury in Japan. If all goes smoothly, the clinical trial of the medicine may begin in 2016.

For the full fiscal 2016 (ending January 31, 2017), we



forecast that the company will post an operating revenue of 800 million Yen, an operating loss of 2,000 million Yen. Based on the assumption that the company will post development support revenue as the clinical trial of SB623 for chronic stroke in the U.S. makes further progress, while total expenses will be slightly more than those for the current fiscal year, due to higher R&D costs. However, we believe that the near-term share price is more likely to be affected by progress of the development of "SB623" and new license agreements in Europe and other regions, rather than the financial results. The price of shares hit an all-time high in mid-May, but has subsequently lost momentum for rising further; we think the market undervalues the company.

We have evaluated the company with reference to Mesoblast Limited, an Australian-based regenerative medicine company. Mesoblast is currently developing a therapeutic product in alliance with an Israel-based partner Teva Pharmaceutical Industries for the treatment of congestive heart failure. The product development has progressed to a Phase 3 clinical trial and in terms of market capitalization; Mesoblast is valued at about 59 billion Yen. However, the share price range estimated by Morningstar U.S. is approximately three times the current traded price and it believes Mesoblast to be more value than its market capitalization. Using a conservative evaluation of twice the current market capitalization (102.8 billion Yen), the price of SanBio shares should come to around 2,300 Yen to match Mesoblast's market capitalization. In consideration of the fact that SanBio engages in the development of medicines for larger scale markets than those of Mesoblast, such as those brain stroke, we believe that the price of SanBio shares has ample potential to rise further. In light of this, we begin our valuation of the company shares with an "Overweight" rating, with an estimated share price range of 2,000 ~ 2,300 yen.

(Hiroyuki Miyamoto)

**Revenue and Earnings Trend** (As of December 10)

	Revenue (Yen Mil)	YoY (%)	Operating Profit (Yen Mil)	YoY (%)	Ordinary Profit (Yen Mil)	YoY (%)	Net Profit (Yen Mil)	YoY (%)	EPS (Yen)
2014-1 Past Results	204	14.1	-584	-	-587	-	-589	-	-15.4
2015-1 Past Results	3,229	1,482.8	2,248	-	2,228	-	1,736	-	44.3
2016-1 Company est.	1,835	▲43.2	-855	-	-838	-	-744	-	-17.5
MS est.	1,835	▲43.2	-855	-	-838	-	-744	-	-17.5
2017-1 MS est.	800	▲56.4	-2,000	-	-2,000	-	-2,000	-	-47.0

### Company Overview

A bio-venture engaging in the development of regenerative cell medicines, SanBio Company Limited went public on April 8, 2015, with its shares listed on Tokyo Stock Exchanges' Mothers Market.

The efficacy of regenerative cell medicines is expected to stimulate and enhance the human body's natural ability to restore or establish mechanisms to regenerate motor, sensory and cognitive functions that have been damaged by disease or accident. Previously, treatment of damaged physical functions has depended on physical therapies, such as rehabilitation therapies; therefore the company may open new ways of treating damaged physical functions through the use of regenerative cell therapies. SanBio's regenerative therapies lie in allogeneic, which refer to the transplantation in patients of other persons' cells. According to the company, the reason for using other humans' cells is that autologous transplantation (using the patient's own cells) tends to take time and varies widely in its therapeutic effects, while allogeneic enable high volume production of consistent quality cells.

Currently the company is proceeding to develop "SB623", its mainstay medicine, for patients with chronic stroke and traumatic brain injury, but it has undergone the preclinical testing for efficacy of the medicine against spinal cord injury and the Parkinson's disease as well. The company is also conducting a study into the medicine's efficacy in the treatment of Alzheimer's disease. In addition to SB623, the company is currently at the preclinical study stage to evaluate the efficacy of "SB618" in the treatment of peripheral nerve damage among others and "SB308" in muscular dystrophy.

### Business Environment and Outlook

Patients with chronic stroke stand at 6.8 million in the U.S. and 1.23 million in Japan, but there is no effective therapy for this disease. Even using the conservative assumption that SB623 will be administered to 5% of U.S. patients and with reference to the market size of other major new drugs, we can see that the medicine has great potential, with its estimated market size amounting to around 1 trillion yen.

SanBio has licensed the application of "SB623" for brain stroke in the U.S. to Dainippon Sumitomo Pharma, while it has awarded the same license in Japan to Teijin Limited. As efficacy of SB623 is highly appreciated, the company has been able to enter into license agreements on more favorable terms compared with general pipeline drugs being developed by other bio-ventures. Under the license agreement with Dainippon Sumitomo Pharma, SanBio will receive US\$80 million (approximately 9.6 billion yen) until SB623 gains official approval, as well as 50% of joint development costs from the pharmaceutical company. Also, following the launch, SanBio will receive royalties at 17% of medicine sales and product supply funds according to the volume of sales.

		Product Pipeline					
Regenerative cell therapy	Applicable disease	Stages prior to human testing		Stages to investigate efficacy and other effects through human testing			
		Research	Preclinical	Approved clinical trial	Phase I	Phase II	Phase III
SB623	Brain stroke (chronic)	[Progress bar from Research to Phase III]					
	Traumatic brain injury	[Progress bar from Research to Phase I (see note)]					
	Age-related macular degeneration (dry)	[Progress bar from Research to Phase I]					
	Retinal pigment degeneration	[Progress bar from Research to Phase I]					
	Parkinson's disease	[Progress bar from Research to Phase I]					
	Spinal cord injury	[Progress bar from Research to Phase I]					
	Alzheimer's disease	[Progress bar from Research to Phase I]					
SB618	Peripheral nerve damage, etc.	[Progress bar from Research to Phase I]					
SB308	Muscular dystrophy	[Progress bar from Research to Phase I]					

(Note) The safety of the medicine for chronic stroke has been confirmed at the clinical trial stage; therefore, the evaluation of the medicine will be undertaken from the Phase II clinical trial.

Source: SanBio financial statements

### Regeneration of brain cells

#### Therapeutic results in the U.S.

Before administration of SB623

The patient was unable to raise her arms

The patient was unable to raise her legs. (she was dependent on a wheelchair in her daily life).

After administration of SB623

She can raise her arms.

She can walk slowly without a wheelchair.

Source: Videos from the International Stroke Conference  
[http://www.youtube.com/watch?v=E4WxwhTp7Ow&feature=c4-overview-v8&list=PL9C2abk3nD4H\\_FNBhItH3m17sc-CD3fG](http://www.youtube.com/watch?v=E4WxwhTp7Ow&feature=c4-overview-v8&list=PL9C2abk3nD4H_FNBhItH3m17sc-CD3fG)

### Risk Factors

The development of ethical pharmaceutical products requires a large amount of R&D expenses and time. However, the development process may face delays, interruptions, postponements or withdrawal without achieving any positive effects or even suffer a postponement or withdrawal. SanBio has licensed the rights to develop and market the "SB623" drug for brain stroke, which the company is currently developing primarily in the U.S. among other countries, to Teijin Limited in Japan and Sumitomo Dainippon Pharma Co., Ltd. in the U.S. and Canada. However, these license agreements may be terminated due to certain reasons.

### Shareholder Return (As of December 10)

#### Dividends

		Dividend Per Share		
		Midterm	Year-End	Annual
2014-1	Past Results	¥0	¥0	¥0
2015-1	Past Results	¥0	¥0	¥0
2016-1	Company est.	¥0	¥0	¥0

#### Shareholder Special Benefits

None

# How to Read Morningstar Equity Research Report

## Our Uniqueness

### (1) Emphasize Its Position as an Independent Evaluation Organization

Morningstar emphasizes its position as an independent evaluation organization and is committed to providing objective comparison and assessment in the Morningstar Equity Research Report. For all stocks covered by us, we determine investment decisions, estimated share price range and earnings forecasts based on expertise of an individual analyst as well as the stock assessment committee consisting of several analysts.

### (2) Universe of Covered Stocks

The stock assessment committee selects covered stocks based on the following criteria.

#### [Stock Selection Criteria]

- Domestic emerging companies that are rarely covered by analysts
- Stocks that are popular among retail investors (refer to data from online security brokers)
- Size of market capitalization (over about 5 billion yen)
- Exclude stocks which are liquidated or trade control, or stocks with going concern and excessive debt

### (3) Investment Decisions Classified into Three Groups

We determine investment decisions for covered stocks after consultation with the stock assessment committee based on research, interview and analysis by each Morningstar analyst.

Each stock is classified into either of three groups according to the following criteria.

**Overweight** : Forecasted to go beyond the current stock price level by 15% or more in the next 6 months.

**Neutral** : Forecasted to fall into the range of -15% ~+15% of the current stock price level in the next 6 months.

**Underweight** : Forecasted to go below the current stock price level by 15% or more in the next 6 months.

We flexibly respond to any changes of observations regarding earnings forecasts, financial situations and stock price trends, and change investment decisions accordingly. "Under Review" status may be applied if any new information comes out and extra time is needed to determine investment decisions. Also we don't change investment decisions during trading hours. "Suspension" status may be applied when an analyst leaves our company.

### (4) Estimated Share Price Range in the Medium Term

It shows the price range for a stock price in the next 6 months. We determine upper and lower range of stock price based on fair value estimates from share price indicator, technical factors such as chart points, most recent high and low prices, trend line and moving average, trading volume in each price range and such.

## Analysis Points

### ■ Analyst Comment

Each analyst reports and evaluates the most recent earnings trend and business environment. It shows the most important information for stock investment such as evidence for investment decisions, perspectives on earnings forecasts and business prospects. Also to make sure it is easy to comprehend, we write in 2-4 paragraphs and use bold to emphasize important texts.

### ■ Revenue and Earnings Trend

It reports earnings in past two fiscal years, company forecasts and our forecasts for the current and next fiscal year. We predict earnings based on research as well as past quarterly earnings trend and analysis by segments.

### ■ Company Overview

It explains in detail what businesses the company is engaged in and how revenue sources are defined. Also on the basis of our research, it discusses what businesses the company will focus on in years to come and how it carries out mid-term business plan.

### ■ Business Environment and Outlook

It discusses current circumstances and growth potential of the industry to which the company belongs. A comprehensive report on the industry from different perspectives is provided through research interviews to competitors. Specific figures of the industry data are also introduced.

### ■ Risk factors

It shows the company's risk factors and describes various aspects of risks such as business, earnings and financials. Typical stock market risks are also taken into consideration.