Kringle Pharma, Inc.

Tokyo Stock Exchange Growth Market code:4884 April 19, 2023

10.8x upside potential based on GCC Management™ analysis

HGF Protein Drugs Could Improve QoL for Billions of People

This report analyzes corporate value from the perspective of GCC Management™," a framework developed by J-Phoenix Research Inc.("JPR") that emphasizes three elements: Growth (sales growth), Connection (improved human and business connections = higher return on capital), and Corporate value analysis from the perspective of GCC Management™, which emphasizes the three elements of Confidence (improved trust = lower business risk)."

Providing innovative therapeutic tools through research and development of drugs for intractable diseases

Kringle Pharma, Inc. ("Kringle") was established in 2001 for the purpose of research and development of pharmaceuticals for intractable diseases, obtained a development license for HGF protein (hepatocyte growth factor) in 2005, started development as a new pipeline, established a post-launch distribution system through a capital and business alliance, and listed on TSE Mothers (currently TSE Growth) in 2020. Currently, Kringle has two pipelines in Phase III trials, which are in the preliminary stage of application for approval, and aims to start sales as soon as possible through the multiple capabilities of HGF and the establishment of a manufacturing method for recombinant proteins.

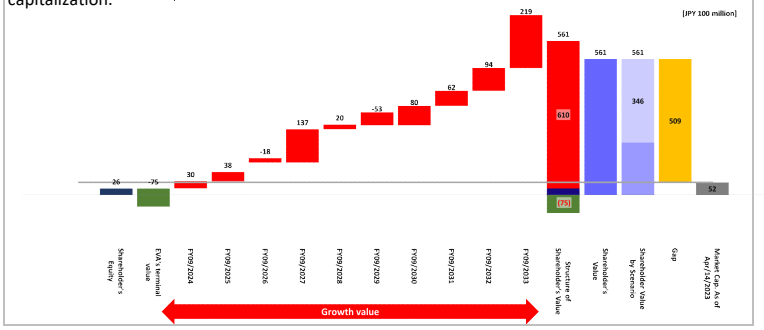
Kringle's HGF protein is an important protein that is deeply involved in the "regeneration" mechanism that is inherent in the human body, and many papers have

Kringle's HGF protein is an important protein that is deeply involved in the "regeneration" mechanism that is inherent in the human body, and many papers have suggested that it could be a potential therapeutic agent for intractable diseases. Kringle believes that HGF is the seed of regenerative drug discovery that can be disseminated from Japan to the world. By supplying HGF as a drug or active pharmaceutical ingredient, Kringle aims to advance research and development of therapeutic drugs for intractable diseases and provide innovative therapeutic means. Kringle will maximize mid- to long-term earnings by combining the models.

The conceptual design*1 is very sophisticated, and once the drug is launched for the acute stage of spinal cord injury in FY09/2025, the feasibility of subsequent development will be sufficiently high. The implementation design*2 is also steadily being developed, with two pipeline products in Phase III trials and the results of collaborative research published in a paper, and is being evaluated by the stock market at this time.

Potential for mainstay stocks related to xxx with a maximum upside of 10.8x

Shareholder value was estimated using the "excess profit method" (see "Reference 2") according to the GCC Management™ framework. As a result, assuming that the concept of the value creation process is implemented and realized, if 10 years of growth value is factored in, shareholder value is JPY 56.1 billion. This is approximately 10.8 times the current market capitalization. Max. Upside Potential ➡ JPY 56.1 billion / JPY 5.2 billion ＝10.8x



For more information on the *1"Conceptual Design "*2"Implementation Design" and the evaluation system, please refer to Reference 1. For those new to JPR reports at the end of this document.

Basic Report

Written and Edited by
J-Phoenix Research Inc.
Taizo Honda

Company Profile	
Location of Head Office	Ibaraki, OSAKA
Representative	Kiichi Adachi
Date of Establishment	December 21, 2001
Paid-in Capital	JPY 59 million
Date of Listing	December 28, 2020
URL	https://www.kringle-pharma.com/en/
Type of Business	Pharmaceutical

Key Indicators As of April 18, 2023	
Stock Price	JPY 1,005
52-week high	JPY 1,325
52-Week Low	JPY 421
Number of Shares Outstanding	5,390,700 stocks
Trading Unit	100 stocks
Market Capitalization	JPY 5,418 million
Company Projected Dividend	JPY -
Estimated Net Income	JPY -177.49
Forecast PER	- times
Actual BPS (September 30, 2022)	JPY 488.23
Actual PBR	2.06 times

Perfomance Trends	Sales (JPY 1 mil.)	YoY %	Operating income (JPY 1 mil.)	YoY %	Ordinary income (JPY 1 mil.)	YoY %	Net income (JPY 1 mil.)	YoY %	EPS (JPY)	Stock price High price (JPY)	Stock price Low price (JPY)
Results for FY 9 2020	467	nm	-171	nm	-116	nm	-117	nm	-106.70	-	-
Results for FY 9 2021	289	-38.2%	-357	nm	-299	nm	-301	nm	-72.51	1,780	937
Results for FY 9 2022	391	35.2%	-426	nm	-330	nm	-331	nm	-68.33	805	419
Results for FY 9 2022 1Q	13	-85.4%	-120	nm	-128	nm	-129	nm	-29.34	919	602
Results for FY 9 2023 1Q	17	25.8%	-157	nm	-157	nm	-157	nm	-29.02	619	421
Plans for FY 9 2023	68	-82.4%	-993	nm	-953	nm	-955	nm	-177.50	-	-

1. Investment Summary

Shareholder value analysis

Maximum Upside 10.8x in Market Capitalization Estimated

Estimation using the excess profit method

Maximum upside 10.8x depending on realization of growth scenario

JPR estimated shareholder value using the "excess profit method" (see "Reference 2") based on the GCC Management ™ framework, taking into account the future prospects regarding Kringle's business development. The following chart visualizes the framework of the qualitative and quantitative stories and the results of the estimation. Assumptions are explained on the following pages.

Shareholder Value Analysis(Unit: JPY 100 million)

Qualitative Story Outline

- Growth: HGF Protein for the Treatment of Intractable Diseases
- Connection: Strengthen profit structure by leveraging existing expertise and value chain
- Confidence: Expectations for social contribution through treatment of intractable diseases

Quantitative Story Outline

Market capitalization	Value gap
52	Maximum upside to market capitalization = 10.8x

Shareholder value reflecting a 10-year growth scenario to the maximum extent possible[1]

Shareholders' Equity26+Excess profit-75+Growth value610= 561

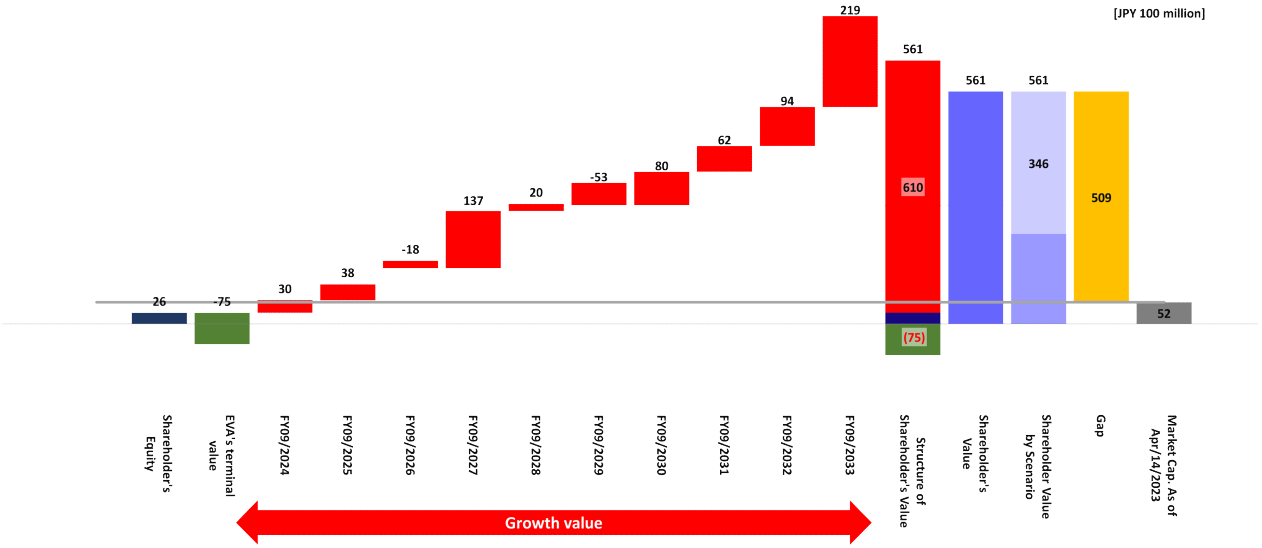
Shareholders'	Excess profit	Growth value
26	-75	610

Source: JPR

1: Fractions do not match due to rounding.

Shareholder Value Structure and Value Gap Analysis Using the Excess Profit Method

Max. Upside Potential ➡ JPY 56.1 billion / JPY 5.2 billion ＝10.8x



Source: JPR

Shareholder Value Structure and Value Gap Analysis Using the Excess Profit Method (details)

[JPY 100 million]	Current Year 2023.09	1 year later 2024.09	2 years later 2025.09	3 years later 2026.09	4 years later 2027.09	5 years later 2028.09	6 years later 2029.09	7 years later 2030.09	8 years later 2031.09	9 years later 2032.09	10 years later 2033.09
Sales	1	11	12	11	41	52	48	81	118	203	429
Operating income	-10	1	1	-2	26	30	17	39	58	90	170
Operating margin	-1460.3%	6.4%	12.2%	-17.0%	63.1%	58.5%	36.2%	48.6%	49.2%	44.2%	39.8%
Sales growth rate	-82.6%	1470.6%	9.4%	-8.6%	280.9%	27.0%	-6.8%	67.4%	46.0%	72.1%	111.5%
NOPAT margin	-1009.6%	4.4%	8.5%	-11.8%	43.6%	40.4%	25.0%	33.6%	34.0%	30.6%	27.5%
Invested capital turnover ratio	452.2%	437.5%	51.2%	55.7%	18.1%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%
WACC	9.5522%	9.5522%	9.5522%	9.5522%	9.5522%	9.5522%	9.5522%	9.5522%	9.5522%	9.5522%	9.5522%
ROIC = NOPAT margin ÷ invested capital net sales ratio	-223.3%	1.0%	16.5%	-21.1%	241.5%	224.6%	139.0%	186.5%	189.1%	169.9%	152.9%
ROIC / WACC (value created with the original hand of 1 yen)	(¥23.4)	¥0.1	¥1.7	(¥2.2)	¥25.3	¥23.5	¥14.5	¥19.5	¥19.8	¥17.8	¥16.0
NOPAT	-6.87	0.47	0.99	-1.26	17.76	20.90	12.05	27.08	40.05	61.92	117.85
Invested capital × WACC	0.29	4.46	0.57	0.57	0.70	0.89	0.83	1.39	2.02	3.48	7.36
EVA	-7.16	-3.99	0.4176	-1.83	17.05	20.01	11.22	25.70	38.03	58.44	110.49
EVA = NOPAT - invested capital × WACC	-7.16	-3.99	0.42	-1.83	17.05	20.01	11.22	25.70	38.03	58.44	110.49
Value created in each year	-75	33	46	-23	198	31	-92	152	129	214	545
Discount Rate	100%	91%	83%	76%	69%	63%	58%	53%	48%	44%	40%
Present value of EVA	**-75**	**30**	**38**	**-18**	**137**	**20**	**-53**	**80**	**62**	**94**	**219**
Invested capital ① Origin	**3**										
Over profit value (Permanent value of EVA of this term) ②	**-75**										
Growth value (Present value of increase in EVA) ③	**610**										
Non-business asset value ④	**26**										
Corporate value = ① + ② + ③ + ④	**564**										
Interest-bearing debt, etc.	**-3**										
Shareholder value	**561**										

Source: JPR

*For NOPAT, since it is difficult to estimate the corporate tax rate, a conservative effective corporate tax rate of 30.9% is applied.

Three qualitative and quantitative information assumptions set for estimating shareholder value*1 (Unit: JPY 100 million)

Growth: HGF Protein for the Treatment of Intractable Diseases

Values and Worldviews	Value provided and Growth Potential	Sales
Realization of unique regenerative medicine	**Expectations for expanding indications in regenerative medicine**	pectations for rapid growth after market laur
Kringle aims to realize the provision of innovative therapeutic means through research and development of therapeutic drugs for intractable diseases. Kringle will respond to the social issue of establishing regenerative medicine that is effective for intractable neurological diseases and fibrosis diseases for which no good drugs have yet been developed, not only by providing its core competence, "HGF," as a drug, but also by supplying active pharmaceutical ingredients.	The total market size of HGF protein products for the acute stage of spinal cord injury, ALS, and vocal cord scarring is estimated to be JPY 35 billion in Japan and JPY 180 billion worldwide. Since HGF is not limited to these areas, but also demonstrates multiple capabilities as a regenerative medicine, further expansion of indications and fusion with IT technology are expected in the future. Rapid growth is expected by acquiring a certain market share in this area.	2023.9 → 2033.9 **0.68** → **429** Assuming the launch of a drug for the acute stage of spinal cord injury in FY09/2025 and the subsequent development of various HGF drugs in Japan and overseas.

Growth value

610

Connection: Strengthen profit structure by leveraging existing expertise and value chain

Strategy	Business Model	ROIC
Maximize revenue through a hybrid model	**zing the Advantages of Protein Pharmaceut**	Expected to improve by 376.2 points
Kringle's goal is to create a model for (1) in-house development and marketing of pharmaceutical products utilizing HGF. While this is expected to increase sales over the long term, it will be costly and time-consuming to start approved sales. Therefore, Kringle aims to maximize mid- to long-term earnings by hybridizing (2) the out-licensing and co-development model, which leads to short-term and sporadic sales, and (3) the API supply model, which generates continuous sales.	While linking basic research at universities to the late-stage pipeline as initiatives (1) + (2), Kringle is also supplying API for HGF to its partner in the U.S. as (3). Because HGF is a protein medicine, it is less expensive and easier to handle than cell therapy and can leverage existing supply chains. Therefore, Kringle has already established a domestic sales and wholesale supply chain for the acute stage of spinal cord injury, and market penetration is expected to be rapid after the product is launched.	2023.9 → 2033.9 **-223.3** % → **152.9** % Assumed wholesale and distribution of marketed HGF medicines through outsourcing.

Excess profit

-75

Confidence: Expectations for social contribution through treatment of intrac

Financial Sustainability	+	Contribution to Social Sustainability	=	WACC
return to profitability through mar		**ons of people expected to improve**		Maintenance of the status quo
Kringle's revenues consist primarily of royalties and product sales of HGF, but there are no medicines currently on the market. At the earliest, KP-100IT medicine for the acute stage of spinal cord injury is expected to be launched in FY09/2025, and once this happens, Kringle will establish its own development and sales model, which will improve profitability. Until the realization of profitability, aggressive development will be pursued by acquiring alliance partners and raising funds through equity financing.		The expansion of the HGF adaptation to intractable diseases such as chronic spinal cord injury and various fibrosis diseases will bring the total number of eligible patients worldwide to 2 billion. These 2 billion people are expected to improve the quality of life (QoL) of patients and those around them by treating or alleviating the symptoms of diseases that were previously untreatable due to technical or financial reasons.		**9.6** %

Currently, the financial situation is relatively unstable. On the other hand, the business and its future potential will contribute greatly to the sustainability of society.

Shareholders' Equity

26

*1Compiled by JPR based on its own projections of post-company plan estimates based on company hearings.

2. Overview

Company overview

Company Name	Kringle Pharma, Inc. (Japanese notation: クリングルファーマ株式会社)
Establishment	December 21, 2001
Representative	Kiichi Adachi
Head Office Location	207 Saito Bio Incubator 7-7-15 Saitoasagi, Ibaraki, OSAKA
Capital	JPY 59 million
Number of Employees	12（As of September 30, 2022）
Fiscal Year End	September
Business	R&D, manufacturing, and sales of HGF-based madicine as a pharmaceutical product
Date of Listing	December 28, 2020
Stock Exchange Listing	Tokyo Stock Exchange Growth Market［Securities code: 4884］

Source: Compiled by JPR based on company data.

History

Year	Month	Contents
2001	12	Established in Kita-ku, Osaka for the purpose of research and development of pharmaceuticals and gene therapy
2005	5	Obtained a license to develop and commercialize HGF protein from Toshikazu Nakamura, Professor Emeritus of Osaka University, and began pharmaceutical development (development code: KP-100)
2007	6	Established a manufacturing method for mass production of Pharmaceutical-grade HGF protein as an active pharmaceutical ingredient
	11	Entered into a joint research agreement and a license agreement with NIPPON ZENYAKU KOGYO CO., LTD. for the purpose of early commercialization of an animal drug consisting of HGF
2018	6	Begins sales of developed recombinant human HGF protein as a research reagent from ReproCELL Corporation
2019	9	Ministry of Health, Labour and Welfare designated HGF protein as an orphan drug for the treatment of acute spinal cord injury
2020	3	Capital and business alliance with TOHO HOLDINGS CO., LTD. for distribution of HGF protein drug in Japan in acute spinal cord injury
	4	Signed a license and supply agreement with Claris Biotherapeutics, Inc. (US)
	8	Capital and business alliance with Maruishi Pharmaceutical Co., Ltd. to commercialize HGF protein in Japan in acute spinal cord injury
	12	Listed on the Mothers Market (currently Growth Market) of the Tokyo Stock Exchange
2021	2	Signed a joint research agreement with Keio University School of Medicine, aiming to an advanced therapy using HGF and other technologies for the treatment of spinal cord injury
	9	“Oremepermin Alfa” was registered as the International Nonproprietary Name (INN) for recombinant human HGF (Development code: KP-100)
2022	4	Market classification changed to Tokyo Stock Exchange Growth
2023	1	In a joint research project with Keio University School of Medicine on combined therapy for chronic complete spinal cord injury, the results of "the world's first successful recovery of motor and urinary functions in a chronic stage of complete spinal cord injury model animals with severed spinal cord nerve fibers by constructing a new neural circuit" were published in the online edition of the international journal "Biomaterials".

Source: Compiled by JPR based on company data.

Major Business and Capital Alliances

Year	Month	Company	Purpose
2020	3	TOHO HOLDINGS CO., LTD.	An agreement for exclusive wholesale distribution of a product being developed by Kringle Pharma for the acute treatment of spinal cord injury when the product receives manufacturing and marketing approval. This alliance establishes a supply chain to supply the product to the market.
2020	4	Claris Biotherapeutics, Inc. (US)	The agreement grants Claris an exclusive license to supply information and API for HGF API to Claris Biotherapeutics, Inc. (US) for the subcutaneous ocular area only. In addition, Kringle holds preferential negotiating rights for a license agreement in Japan with respect to Clarisse's development items.
2020	8	Maruishi Pharmaceutical Co., Ltd.	The agreement grants Kringle Pharma the exclusive rights to market a product under development for the acute stage of spinal cord injury when it obtains manufacturing and marketing approval. This alliance will establish a sales network for the product.

Source: Compiled by JPR based on company data.

Development Pipeline Overview

Priority	Target Diseases	Development Stage	Clinical trials			Application Approval	Sales
			Phase I	Phase II	Phase III		
1	Spinal Cord Injury Acute phase	Phase I/II (Placebo-controlled double-blind comparative study) Completed, POC obtained, Orphan Drug Designation obtained, Phase III study ongoing POC obtained, Orphan Drug Designation obtained, Phase III study ongoing.	Completed		Ongoing	Scheduled to end in late 2023	
2	Vocal cord scarring	Phase I/II (open-label dose escalation study, investigator-initiated clinical trial) Phase III (placebo-controlled, double-blind, placebo-controlled, placebo-controlled, double-blind, placebo-controlled, placebo-controlled, placebo-controlled) Phase III (placebo-controlled, double-blind comparative study) started.	Completed		Ongoing	Starts November 2022	
3	ALS	Phase II (placebo-controlled, double-blind, investigator-initiated clinical trial) Completed, no statistically significant differences in primary and secondary endpoints, additional analysis planned. No significant difference in primary and secondary endpoints, additional analysis to be performed.	Completed	Completed	Additional analysis to be conducted		
4	Acute kidney injury	Phase Ia, b (open-label dose escalation study) Completed, safety and pharmacokinetics confirmed. Searching for a partner.	Completed	Searching for			

Source: Compiled by JPR based on company data.

3. Growth Story and Assessment through the GCC Management™ Framework

Growth

Conceptual design is solidified and the logic is of high social value

Progress: 90%

Market launch is imminent
Progress: 70%

Reflection of results in
Progress: 10%

Expectations for Expansion of Indications from Launch of Own Pipeline

Conceptual design: "New drugs for patients, smiles for people"

Kringle aims to realize the provision of innovative therapeutic means through research and development of therapeutic drugs for intractable diseases. To address the social issue of establishing regenerative medicine that is effective for intractable neurological diseases and fibrosis diseases, etc. for which no good medicine has yet been developed, Kringle will not only provide our core competence, developmental seed HGF, as a pharmaceutical product, but also supply active pharmaceutical ingredients. HGF is an important protein that is deeply involved in the "regeneration" mechanism that is inherent in the human body, and many papers have suggested that it may be a potential therapeutic agent for intractable diseases. Kringle believes that this is a regenerative drug discovery seed that can be disseminated from Japan to the world.

SAM: JPY 20 trillion from current targeted diseases only

The HGF protein product market is estimated to be worth JPY 35 billion in Japan and JPY 180 billion worldwide for the main pipeline products for the acute stage of spinal cord injury, ALS, and vocal cord scarring. The global market is estimated to be up to JPY 20 trillion due to the expansion of HGF into the chronic stage of spinal cord injury and from vocal cord scarring to other fibrosis diseases.

TAM: Further expansion in the area of neurology and intractable diseases in general

The potential for expansion of the indications for HGF regenerative therapies offered by Kringle is very high and could cover a variety of intractable diseases in the neurological area, including dementia and stroke, as well as vascular disorders and asthma. Since the number of patients suffering from these diseases is much larger than the current target diseases, TAM is expected to exceed SAM's JPY 20 trillion by a wide margin.

Implementation design: 2 pipelines with Phase III trials in progress

Kringle currently has two pipeline products in Phase III trials (for acute spinal cord injury and vocal cord scarring), which are in the final stages of drug development and prior to regulatory approval. As of April 13, Kringle had completed patient enrollment in Phase III trials for the acute stage of spinal cord injury, and expects to launch the drug in FY09/2025 at the earliest. Once the product is launched, it is expected to generate up to 10 billion yen in revenues as its market share expands.

Performance: Technology Access Fee is the current performance.

(Bulk) drug substance supply for HGF is in place and a fixed annual technology access fee is received from Claris, Inc. of the United States.

Connection

From a drug discovery venture to a biopharmaceutical company by establishing a profit model

Conceptual Design: Realization of a Hybrid Profit Model

The conceptual design is solidified.

Progress: 90%.

Kringle's goal is to achieve a model of (1) in-house development and marketing of HGF-based drugs. While this is expected to expand sales over the long term, it will be costly and time-consuming until the approval and start of sales. Therefore, the company aims to maximize mid- to long-term earnings by hybridizing (2) the out-licensing and co-development model, which leads to short-term and sporadic sales, and (3) the API supply model, which generates continuous sales. As part of the initiatives (1) + (2), the company is linking basic research at universities to the late-stage pipeline, while at the same time supplying API for HGF to Claris Pharmaceuticals in the U.S. as part (3).

Implementation Design: Differentiation by HGF and establishment of a system to accelerate the launch of the product

Establish competitive advantage as Protein Pharmaceuticals

High competitive advantage and feasibility

Progress: 70%.

Pharmaceuticals are broadly classified into small molecule drugs, Protein Pharmaceuticals, cellular therapeutics, etc. In the two pipelines undergoing Phase III trials, the only protein drug in active development that is not an antibody drug is Kringle's HGF protein, as far as disclosed information is concerned, while the others are antibody drugs or cellular therapeutics.

While antibody drugs treat by inhibiting a specific part of the body's functions, HGF proteins treat by enhancing regenerative functions of human origin, and thus have the potential to be developed in a variety of ways as multi-functional drugs. While cell therapy drugs are expensive and can only be used in a few medical institutions due to administrative issues, Protein Pharmaceuticals can be distributed as lyophilized preparations, which are relatively inexpensive and can be used in emergency hospitals nationwide. These advantages give HGF an advantage over competing products.

Utilize existing know-how and supply cha

Since HGF is a Protein Pharmaceutical, the existing supply chain can be utilized. Therefore, Kringle has already established a wholesale distribution system for the KP-100IT drug through a capital and business alliance with Toho Holdings, Inc. and a sales system through a capital and business alliance with Maruishi Pharmaceutical Co., Ltd.

Achievements: Progress in Collaborative Research

Research progress has a positive impact on stock price

Reflected in results

Progress: 30%

On January 26, 2023, the results of the joint research on combined therapy for chronic stage complete spinal cord injury were published in an article in the online edition of the international journal Biomaterials. The combined therapy using iPS cell-derived neural stem/progenitor cells owned by Keio University and HGF and scaffold (scaffold base material) developed by Kringle successfully restored motor function and urinary function by building new neural circuits in the chronic stage of complete spinal cord injury model animals whose spinal cord nerve fibers were severed, for the first time in the world. This is the first success in the world.

Confidence

Return to profitability in the next fiscal year or later
Current stability is 10%.

Funding to accelerate growth investments

There is a great need for treatment of intractable diseases, and expanding the indication to include dementia would be in line with national policy.

It could be said to be about 90% as a social contribution.

Expected to contribute to society by expanding the application of the product.

Financial Stability: Aiming to return to profitability through market launch

Expected to be launched in FY09/2025 at the earliest.

Kringle's revenues consist mainly of royalties and product sales of HGF, but no drugs have been launched at present. The company expects to launch its KP-100IT drug for acute spinal cord injury in FY09/2025 at the earliest, and once this happens, the company will have established its own development and sales model, which will improve its revenues. Similarly, a pharmaceutical for vocal cord scarring is undergoing Phase III trials, so the company's earnings should stabilize over the medium to long term as it continues to develop new drugs that utilize HGF.

Funding to accelerate growth investments

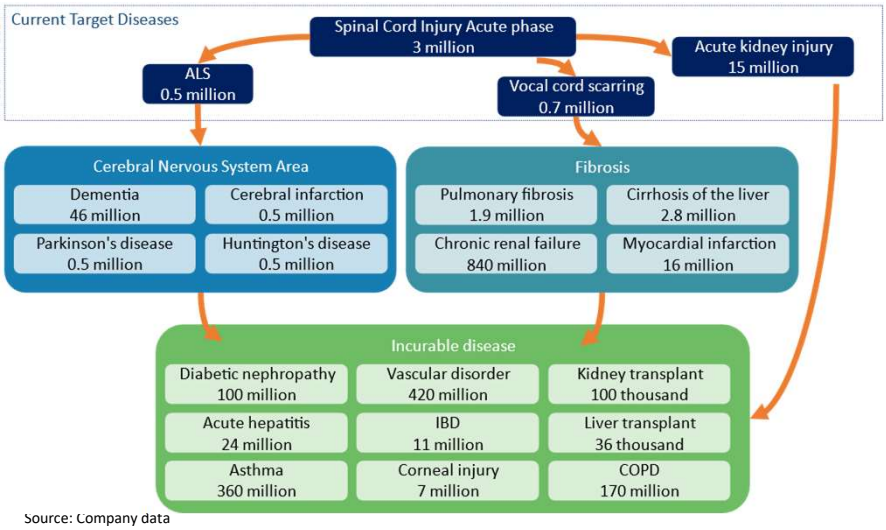
In order to continue aggressive development, it will be necessary to acquire alliance partners, raise funds through equity financing, etc., depending on the financial situation. Given that the company will not return to profitability until the next fiscal year at the earliest, equity financing, not debt, is expected to be used for the time being.

Social contribution: Improvement of QoL of patients and surrounding people through treatment of intractable diseases

Billions of people expected to improve QoL

The expansion of the HGF indication to intractable diseases such as chronic spinal cord injury and various fibrosis diseases will bring the treatment to a significant number of patients worldwide. These patients will be able to treat or alleviate the symptoms of diseases that could not be treated due to technical or financial reasons, thereby improving the quality of life of the patients and the people around them.

Potential expansion of indications for HGF regenerative therapies/number of eligible patients worldwide



Source: Company data

4. Summary of Business Results for 1Q FY2023

Financial Summary

Overall Overview

Profit and Loss Summary

Sales were JPY 17 million (up 25.8% y-o-y), and operating loss was JPY 157 million (vs. an operating loss of JPY 120 million in the same period of the previous year). The recurring loss was JPY 157 million (vs. recurring loss of JPY 128 million in Q1 FY09/2022), and net loss was JPY 157 million (vs. net loss of JPY 129 million in Q1 FY09/2022).

Pharmaceutical Development Activities

Spinal Cord Injury (SCI) Acute

The Phase III study for patients with acute spinal cord injury has been conducted at a total of 5 sites, and patient enrollment continued during the 1Q cumulative period. Patient enrollment is expected to be completed in the first half of 2023, with the final patient follow-up in the second half of 2023. In order to obtain a manufacturing and marketing approval for the marketed drug, trial manufacturing of the drug substance was completed in the previous fiscal year. Pharmaceutical formulation manufacturing is progressing according to plan.

Vocal Fold Scarring (VFS)

In October 2022, a notification of clinical trial plan for a Phase III study (placebo-controlled double-blind comparative study) for VFS, a disease that causes hardening and degeneration (fibrosis) of the vocal fold mucosa, was submitted to and accepted by the PMDA. The clinical trial was then initiated at Kyoto Prefectural University of Medicine Hospital, and the first subject was enrolled in January 2023.

Amyotrophic Lateral Sclerosis (ALS)

No statistically significant differences were found between the actual drug group and the placebo group with respect to the primary and secondary endpoints for the Phase II study, for which the final observation date for the last patient was December 2021. The future direction of the study will be decided in consultation with Tohoku University based on the results of further detailed analysis.

Drug substance provision

No HGF API was supplied to Claris Pharmaceuticals, Inc. of the U.S. in the current 1Q cumulative period. ' Fixed amount of technology access fee (royalty income) was received and recorded in net sales for the relevant period. Claris Pharmaceuticals, Inc. is conducting Phase I/II studies for neurotrophic keratitis in the U.S. and Canada. The company expects to accelerate case enrollment in the U.S. and Canada.

Business Development Activities

With a view to overseas expansion in the acute phase of spinal cord injury, business development activities focused on business alliance discussions with overseas pharmaceutical companies and others.

5. Reference material: Details of the financial model

Detailed financial model of actual results, company plan and JPR forecast 10-year forecast

	(Unit: JPY million)	Company Plans JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast
FY		2023.09	2024.09	2025.09	2026.09	2027.09	2028.09	2029.09	2030.09	2031.09	2032.09	2033.09
PL	Sales	68	1,068	1,168	1,068	4,068	5,168	4,817	8,066	11,774	20,262	42,860
	COGS	0	0	25	250	500	772	1,162	1,675	2,291	4,444	10,008
	SGA	1,061	1,000	1,000	1,000	1,000	1,372	1,912	2,474	3,690	6,862	15,806
	EBITDA											
	Total depreciation and amortization											
	OP	▲ 993	68	143	▲ 182	2,568	3,023	1,743	3,917	5,793	8,956	17,046
	Interest rate	0	0	0	0	0	0	0	0	0	0	0
	Other non-OP	40	0	0	0	0	0	0	0	0	0	0
	CP	▲ 953	68	143	▲ 182	2,568	3,023	1,743	3,917	5,793	8,956	17,046
	Extraordinary Profit/loss	24	0	0	0	0	0	0	0	0	0	0
	NP before taxes and minority	▲ 929	68	143	▲ 182	2,568	3,023	1,743	3,917	5,793	8,956	17,046
	Tax	26	21	44	▲ 56	792	933	538	1,209	1,788	2,764	5,260
	NP	▲ 955	47	99	▲ 126	1,776	2,090	1,205	2,708	4,005	6,192	11,785
	Number of shares issued and outstanding at the beginning of the period (thousand shares)	5,381	5,391	5,391	6,199	6,199	6,199	6,819	6,819	6,819	6,819	6,819
	Number of shares issued (thousand shares)	10	0	809	0	0	620	0	0	0	0	0
	Number of shares issued and outstanding at the end of the period (thousand shares)	5,391	5,391	6,199	6,199	6,199	6,819	6,819	6,819	6,819	6,819	6,819
	EPS(JPY)	-177	9	16	-20	286	306	177	397	587	908	1,728
	Dividend	0	0	0	0	0	627	482	1,625	2,804	6,192	11,785
	Retained Earning	▲ 955	47	99	▲ 126	1,776	1,463	723	1,083	1,202	0	0
BS	Operating cash	134	146	134	509	646	602	1,008	1,472	2,533	5,358	9,007
	Excess cash	1,543	1,505	5,104	4,438	6,016	14,573	14,712	15,129	14,804	10,741	5,492
	Working Capital	500	600	146	557	708	660	1,105	1,613	2,776	5,871	9,871
	Short-term investment securities	0	0	0	0	0	0	0	0	0	0	0
	Tangible Fixed Assets	0	0	0	0	0	0	0	0	0	0	0
	Goodwill	0	0	0	0	0	0	0	0	0	0	0
	Software	0	0	0	0	0	0	0	0	0	0	0
	Investment securities	0	0	0	0	0	0	0	0	0	0	0
	Other assets	1	1	1	1	1	1	1	1	1	1	1
	Total Assets	2,178	2,252	5,384	5,505	7,371	15,836	16,826	18,214	20,114	21,971	24,371
	NIBCLs	88	96	88	334	425	396	663	968	1,665	3,523	5,923
	ST debt	0	0	0	0	0	0	0	0	0	0	0
	LT debt	0	0	0	0	0	0	0	0	0	0	0
	Other long-term liabilities	256	256	256	256	256	256	256	256	256	256	256
	Paid Capital	3,116	3,135	6,177	6,177	6,177	13,208	13,208	13,208	13,208	13,208	13,208
	Retained Earnings	▲ 1,282	▲ 1,235	▲ 1,136	▲ 1,262	514	1,977	2,700	3,783	4,984	4,984	4,984
	Debt&Equity	2,178	2,252	5,384	5,505	7,371	15,836	16,826	18,214	20,114	21,971	24,371
CF	Operating cash	▲ 125	▲ 13	13	▲ 375	▲ 137	44	▲ 406	▲ 464	▲ 1,061	▲ 2,825	▲ 3,650
	Working Capital	▲ 49	▲ 100	454	▲ 411	▲ 151	48	▲ 445	▲ 508	▲ 1,163	▲ 3,096	▲ 4,000
	NIBCLs	▲ 74	8	▲ 8	247	90	▲ 29	267	305	698	1,857	2,400
	Gross Investment	0	0	0	0	0	0	0	0	0	0	0
	Depr	0	0	0	0	0	0	0	0	0	0	0
	Software Investment	0	0	0	0	0	0	0	0	0	0	0
	Software amortization	0	0	0	0	0	0	0	0	0	0	0
	Goodwill investment	0	0	0	0	0	0	0	0	0	0	0
	Amortization of goodwill	0	0	0	0	0	0	0	0	0	0	0
	Short-term marketable securities	0	0	0	0	0	0	0	0	0	0	0
	Investment securities	0	0	0	0	0	0	0	0	0	0	0
	Other assets	0	0	0	0	0	0	0	0	0	0	0
	Retained Earnings	▲ 955	47	99	▲ 126	1,776	1,463	723	1,083	1,202	0	0
	CF from operation	▲ 1,203	▲ 57	557	▲ 665	1,578	1,526	139	417	▲ 325	▲ 4,063	▲ 5,250
	ST debt	0	0	0	0	0	0	0	0	0	0	0
	LT debt	0	0	0	0	0	0	0	0	0	0	0
	Other long-term liabilities	0	0	0	0	0	0	0	0	0	0	0
	Equity financing	0	19	3,042	0	0	7,031	0	0	0	0	0
	CF from finance	0	19	3,042	0	0	7,031	0	0	0	0	0
	Increase in Excess Cash	▲ 1,203	▲ 39	3,599	▲ 665	1,578	8,557	139	417	▲ 325	▲ 4,063	▲ 5,250

	(Unit: JPY million)	Company Plans JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast	JPR forcast
FY		2023.09	2024.09	2025.09	2026.09	2027.09	2028.09	2029.09	2030.09	2031.09	2032.09	2033.09
KPI	Ratio to net sales of invested capital at the beginning of the period	437.5%	51.2%	55.7%	18.1%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%
	Invested capital at the beginning of the period	297.5	546.7	651.0	193.0	732.4	930.1	867.1	1,451.2	2,117.9	3,644.0	7,707.0
	sales growth	-82.6%	1470.6%	9.4%	-8.6%	280.9%	27.0%	-6.8%	67.4%	46.0%	72.1%	111.5%
	NOPAT	-687	47	99	-126	1,776	2,090	1,205	2,708	4,005	6,192	11,785
	ROIC	-230.8%	8.6%	15.2%	-65.2%	242.4%	224.7%	139.0%	186.6%	189.1%	169.9%	152.9%
	Working Capital DOH	2,421	171	50	50	50	50	50	50	50	50	50
	COGS/Sales	0.0%	0.0%	2.1%	23.4%	12.3%	14.9%	24.1%	20.8%	19.5%	21.9%	23.4%
	NIBCLs DOH	870	30	30	30	30	30	30	30	30	30	30
	CASH required	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
	ST interest rate	1.48%	1.48%	1.48%	1.48%	1.48%	1.48%	1.48%	1.48%	1.48%	1.48%	1.48%
	DT interest rate	1.50%	1.50%	1.50%	1.50%	1.50%	1.50%	1.50%	1.50%	1.50%	1.50%	1.50%
	Tax rate	30.9%	30.9%	30.9%	30.9%	30.9%	30.9%	30.9%	30.9%	30.9%	30.9%	30.9%
	Pay out ratio	0.0%	0.0%	0.0%	0.0%	0.0%	30.0%	40.0%	60.0%	70.0%	100.0%	100.0%
	Gross DE Ratio	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	Net DE Ratio	-91.4%	-86.9%	-103.9%	-100.7%	-99.6%	-99.9%	-98.8%	-97.7%	-95.3%	-88.5%	-79.7%
	Depreciation rate of property, plant and equipment	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	Amortization rate of goodwill	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%
	Depreciation Ratio	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: JPR

Reference 1. For those new to JPR reports

GCC Management™ Analysis

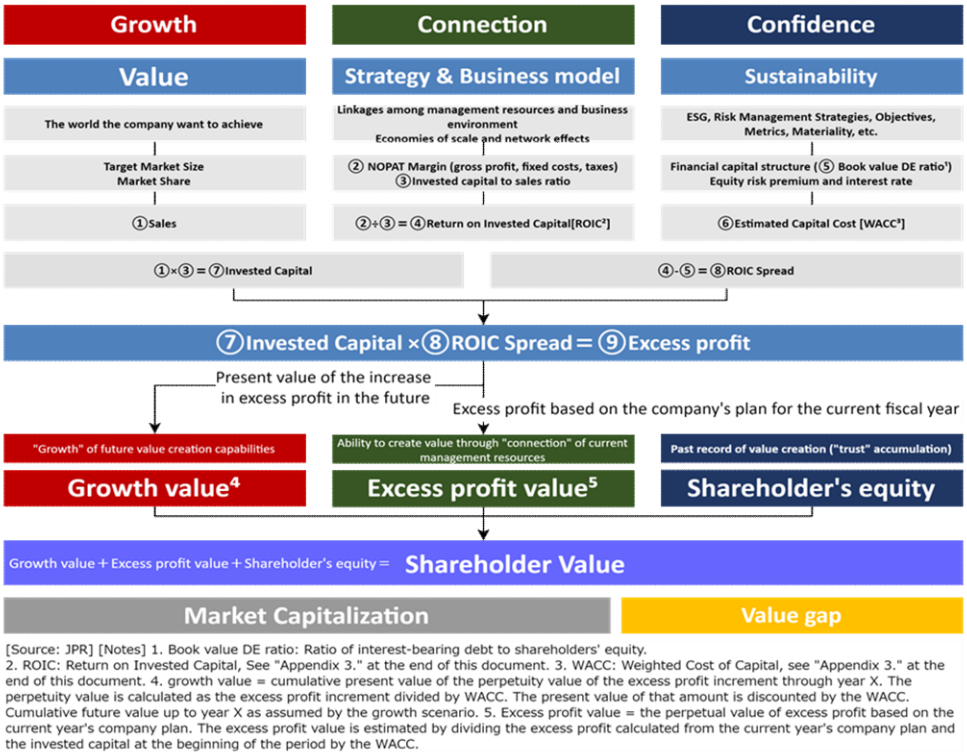
Visualize the value gap between theoretical shareholder value and market capitalization

Analyze by the three elements of Growth, Connection, and Confidence.

A framework for directly linking qualitative stories to shareholder value

This report analyzes corporate value from the perspective of GCC Management™, a framework developed by J-Phoenix Research Inc. ("JPR"), emphasizing three elements: Growth (sales growth), Connection (improved human and business connections = higher return on capital), and Confidence (improved trust = lower business risk). The following chart shows the overall picture of the GCC Management™ framework. The following diagram shows the overall picture. The qualitative future story is linked to financial indicators, which are finally integrated to estimate shareholder value. Using the excess profit method (see "Appendix 3. Basis of Calculation" at the end of this report), JPR estimates the final theoretical shareholder value and visualize the value gap by comparing it with the market capitalization.

GCC Management™ Analysis Framework



[Source: JPR] [Notes] 1. Book value DE ratio: Ratio of interest-bearing debt to shareholders' equity.
2. ROIC: Return on Invested Capital, See "Appendix 3." at the end of this document. 3. WACC: Weighted Cost of Capital, see "Appendix 3." at the end of this document. 4. growth value = cumulative present value of the perpetuity value of the excess profit increment through year X. The perpetuity value is calculated as the excess profit increment divided by WACC. The present value of that amount is discounted by the WACC. Cumulative future value up to year X as assumed by the growth scenario. 5. Excess profit value = the perpetual value of excess profit based on the current year's company plan. The excess profit value is estimated by dividing the excess profit calculated from the current year's company plan and the invested capital at the beginning of the period by the WACC.

Source: JPR

GCC Management™ Evaluation System

Evaluate the feasibility of the Growth and Connection story of the value creation process from three perspectives

Evaluation of Growth and Connection

Evaluate the feasibility of qualitative stories from three perspectives

JPR evaluates the feasibility of the value creation process based on GCC analysis from three perspectives: conceptual design, implementation design, and actual performance. "Conceptual design" is defined as "conceptualizing the concept of the value creation process" and "implementation design" is defined as "creating and operating a system to systematize and implement the management resources necessary to realize the concept of the value creation process. Value creation becomes an "achievement" only when "conceptual design" becomes "implementation design. JPR conducts subjective evaluations of "conceptual design," "implementation design," and "performance," which are then rated in an easy-to-understand manner at 90%, 70%, 50%, 30%, and 10%. Specifics are described below.

Conceptual Design," "Implementation Design," and "Performance" Evaluation Framework

% indication	90%	70%	50%	30%	10%
”Conceptual design”	Conceptual design is very logically organized	Conceptual design is approximately logically organized	Conceptual design is about halfway organized	Conceptual design is organized to a certain degree	Conceptual design is organized to a certain degree
”Implementation design”	Conceptual design is almost implemented	Conceptual design is almost implemented	Conceptual design is about half implemented	Conceptual design is implemented to a certain degree	Conceptual design has been implemented, albeit marginally.
”Performance”	Targeted outcomes are observed as actual results almost exactly as intended by the conceptual design	Targeted outcomes are observed as actual results almost exactly as intended by the conceptual design	Targeted outcomes are observed as actual results as intended by the conceptual design about half way through	Targeted outcomes are observed as actual results to a certain degree, as intended by the design	Targeted outcomes are observed as achievements, albeit slight, as intended by the conceptual design

Source: JPR

Evaluation of Confidence

Evaluation of financial stability and social contribution

Credibility of the value creation process

JPR evaluates the feasibility of the value creation process based on GCC analysis from three perspectives: “Conceptual Design”, “Implementation Design”, and “Actual Performance.” "Conceptual Design" is defined as "conceptualizing the concept of the value creation process" and "Implementation Design" is defined as "creating and operating a system to systematize and implement the management resources necessary to realize the concept of the value creation process.” Value creation becomes an " Actual Performance" only when "Conceptual Design" becomes "Implementation Design. ” JPR conducts subjective evaluations of "Conceptual Design," "Implementation Design," and " Actual Performance," which are then rated in an easy-to-understand manner at 90%, 70%, 50%, 30%, and 10%. Specifics are described below.

"Conceptual Design," "Implementation Design," and " Actual performance" Evaluation Framework

% indication	90%	70%	50%	30%	10%
Financial Stability The evaluation is based on a five-point scale from the viewpoint of sufficient experience in the value creation process, differentiated value creation capabilities that are difficult to imitate, low risk of fluctuations such as economic and seasonal fluctuations due to stockholding, and an optimized capital-liability structure.	**Very Highly commendable**	**Highly commendable**	**Can be evaluated as a listed company on average**	**Can be commendable to a certain degree**	**Partially commendable**
Social Contribution The social issues addressed are generally of great importance to society, the path to their solution is not yet clear, and they are tackling a challenging task that requires both the creation of a new concept and the systematic creation of the optimal governance structure for its implementation.	**Very Highly commendable**	**Highly commendable**	**Can be evaluated as a listed company on average**	**Can be commendable to a certain degree**	**Partially commendable**

Source: JPR

Visualization of value gap through 10-year growth scenario analysis

Comparison of increase in shareholder value and market capitalization by year

Visualize how many years of future stories are reflected in the market capitalization

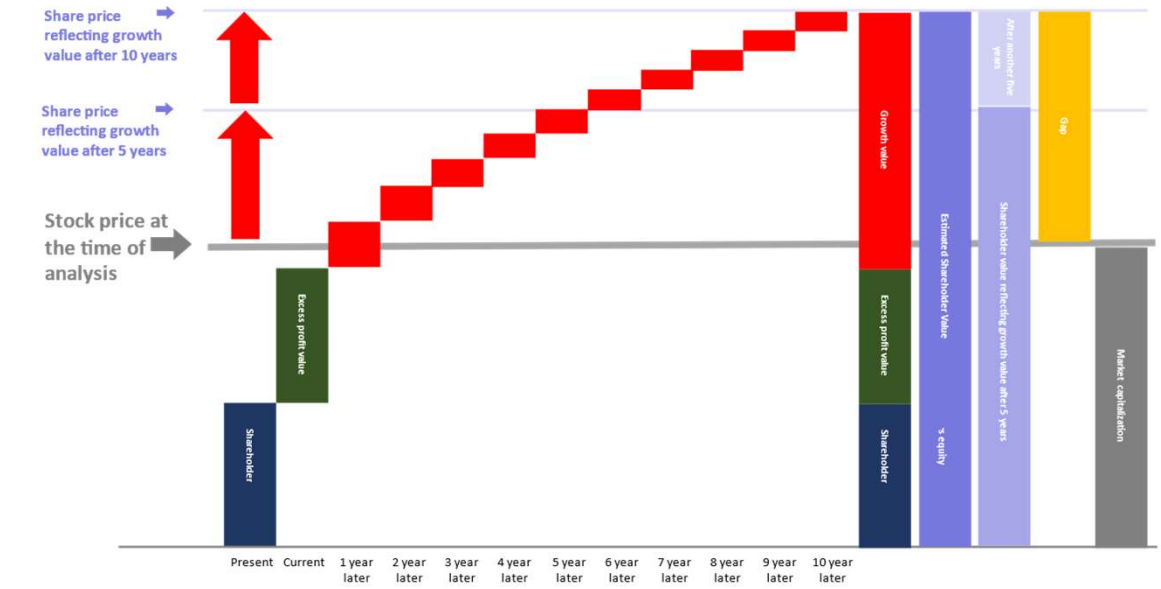
The potential increase in shareholder value generated by a 10-year growth scenario based on the future story is visualized for each year and compared to the market capitalization. This allows us to visualize how many years of the future story are reflected in the market capitalization. 10 years of shareholder value is expected to be reflected in the market capitalization as the expectations for the achievability of the 10-year future story increase. The difference between the market capitalization and the estimated shareholder value reflecting up to 10 years of future story is the estimated upside potential. As investors' expectations of the feasibility of the future story are raised by the specific current performance, the likelihood of the realization of that value gap increases.

Conservative Growth Scenarios and Scenarios Reflecting Change in Future Stories

Visualization of various scenario analysis

This analysis is useful when the firm's strategy undergoes significant change. As shown in the figure below, it is also possible to visualize separately the growth potential under the conservative scenario and the growth potential under the change. Shareholder value without incorporating change represents a conservative amount.

Visualizing the Value Gap



Source: JPR

Reference 1. Basis of Calculation

Corporate value estimated by use of ROIC and excess return

Excess return analysis framework

Excess profit or economic value added is globally used as an indicator to estimate corporate value, evidenced by its adoption by Kao Corporation, a Grand Prix winner of the Tokyo Stock Exchange Fifth Corporate Value Improvement Award (FY2016). In the calculation of excess return, corporate value can be broken down into four elements: invested capital, excess return value, growth value, and non-business assets. This facilitates a better understanding of the structure that creates corporate value. A company might be overvalued or undervalued when its market cap is higher or is lower than its theoretical corporate value, respectively. The contribution of each year's corporate value can be visualized in the following figure, wherein shareholders' equity is simply represented as a sum of invested capital and non-business asset, subtracting interest-bearing debts. The figure below allows us to estimate how many years of growth might be incorporated into the stock price.

Breakdown of corporate value using excess return

[source] JPR

Estimated excess return is profit that exceeds investors' return expectations against invested capital. Its present value is “excess return value,” while a potentially growing portion of excess return is “growth value.” Moreover, assets not used in business are added as non-business asset value in estimating a theoretical corporate value. Theoretically, the estimated corporate value using excess return should be the same as the value estimated using the discount cash flow (DCF) model. This report calculates excess return by using the following figures in a simplified manner.

- Excess return = NOPAT – Invested capital X WACC
- Net Operating Profit After Tax (NOPAT) = Operating profit X (1 - Effective tax rate)
- Invested capital = Total assets – Non-business assets – Current liabilities excluding Interest-bearing debt
- Non-business assets = Cash and deposits exceeding 10% of sales + Short-term investment securities + Investment securities + Deferred gains or losses on hedges + Land revaluation difference + Foreign currency translation adjustments
- Weighted average cost of capital (WACC) = After-tax interest rate of interest-bearing debt X(D/ (E+D)+Cost of shareholders' equity X(E/D+E)
- Cost of shareholders' equity=0.5%+5%Xβ
- β = Slope of a linear regression line of five-year daily returns of TOPIX and the stock price of the target company
- E = Market cap at the time of calculation
- D = Short-term interest-bearing debt + Long-term liabilities + Minority interests in the latest financial statements at the time of calculation

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