

# I'rom Group Co., Ltd.

(Listing the First Section of Tokyo Stock Exchange, #2372)

August 7, 2018

### Being engaged in every process of clinical development, I'rom Group has high

### growth potential with hard-to-imitate competitive advantages

### Moving forward with the goal of building tomorrow's healthcare

With the corporate philosophy "Moving forward with the goal of building tomorrow's healthcare," I'rom Group Co., Ltd. (hereinafter referred to as "I'rom Group") was founded as a pioneer SMO in 1997, with the aim of enabling patients to use the latest medicine with ease, and as soon as possible. At present, besides the SMO Business and the CRO Business, I'rom Group is engaged in businesses, including the Advanced Medicinal Treatment Business, providing regenerative medicine and gene therapy drug discovery technologies and developing gene therapeutic preparations. I'rom Group has established competitive advantages in all clinical development processes, which are hard to be imitated.

### Double impacts from greater cash generation and speedy development

I'rom Group uses its cash generating power, accumulated knowhow in clinical trials, and network with medical institutions in the SMO and CRO Business areas to speed up R&D for gene therapeutic preparations in the Advanced Medicinal Treatment Business. At the same time, the latter business' network with universities and research institutes contributes to expansion in the former businesses and their cash generation power. A virtuous cycle of impacts from all areas can be expected.

# Full-scale growth strategy leading to boost for shareholder value

I'rom Group strives (1) to operate clinical-use vector manufacturing facilities at their full capacity for gene therapy and regenerative medicine; (2) to expand pipelines for gene therapy and cell therapy and accelerate clinical trial operations; and (3) to make its core technologies a de-facto standard in Japan and overseas through proactive out-licensing. By taking these initiatives in and after fiscal 2018, the movement to capture the growth potential of the regenerative medicine field, which is expected to grow by about 30% per annum, will become full-scale in I'rom Group. Assuming about 20% annual sales growth up to fiscal 2024 and an increase in operating margin from 10% at present to 20%, the estimated shareholder value is about \$55 billion, implying an upside potential of doubling in its stock price.

Fiscal Item	Sales	ΥοΥ	Operating income	ΥοΥ	Ordinary income	YoY	Net Income	ΥοΥ	EPS	Diluted EPS	Term-enc ¥ share	
	¥mn			%				%	¥	¥	High	Low
March 2015	4,134	3.1%	-722	NM	-600	NM	-606	NM	-59.10	-	2,772	665
March 2016	4,114	-0.5%	-480	NM	-807	NM	-868	NM	-81.90	-	2,340	688
March 2017	4,890	18.9%	212	moving into the black	272	moving into the black	204	moving into the black	18.80	18.70	1,730	920
March 2018	8,621	76.3%	1,044	392.5%	1,092	301.5%	1,558	663.7%	135.40	132.10	3,500	1,105
March 2019 Est.	11,500	33.4%	1,200	14.9%	1,200	9.9%	700	-55.1%	60.80	-	-	-

**Basic report** 

Written and Edited by J-Phoenix Research Inc.

Corpora	te Profile
Headquarters	Chiyoda-ku Tokyo
President CEO	Toyotaka Mori
Established	April 9, 1997
Capital	¥3,513 million
Listed	January 2005
URL	www.iromgroup. co.jp
Industry	Service
	dicators
(as of Aug	ust 6, 2018)
Stock Price	1,838 yen
Highest in 52 weeks	3,545 yen
Lowest in 52 weeks	1,507 yen
Outstanding	11,703,665
Shares	Stocks
Trading Units	100 Stocks
Market Capitalization	¥21,511million
Prospective Dividend	20.0 yen
Estimated Profit Base EPS	60.80 yen
Estimated PER	30.2 Times
Actual BPS (March 2018)	485.67 yen
Actual PBR	3.8 Times

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#### 1. **Executive Summary**

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# **Extensive** clinical development involvement

Four businesses engaged in every process of clinical development

## Four selfdeveloped pipelines to realize a significant sales growth

Hard-to-imitate competitive advantages to respond to advanced medical needs in regenerative medicine with a 28%<sup>3</sup> annual growth potential

### Involved in every process of clinical development to achieve high growth

With the corporate philosophy "Moving forward with the goal of building tomorrow's healthcare," I'rom Group was founded as a pioneer Site Management Organization (SMO)<sup>1</sup> in 1997, with the aim of enabling patients to use the latest medicine with ease, and as soon as possible. I'rom Group, since then, has expanded its business activities and portfolio. Since fiscal 2013, it has made strategic investments and is now engaged in every clinical development process with its four business units as stated below.

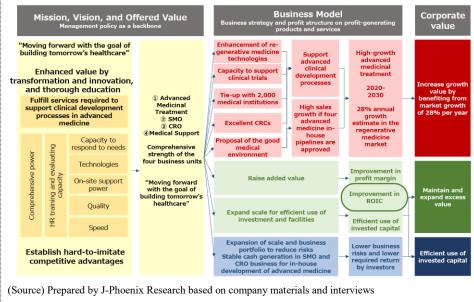
- Site Management Organizations support specialized tasks needed at medical institutions that conduct clinical trials for a drug to be approved by the Ministry of Health, Labour and Welfare
- Four business units engaged in every process of clinical development
- Advanced Medicinal Treatment Business: Provision of regenerative medicine and 1. gene therapy drug discovery technologies; development of gene therapeutic preparations
- 2. SMO Business: Support of clinical trials conducted by medical institutions
- 3. CRO<sup>2</sup> Business: Support of clinical trials conducted by pharmaceutical companies in Japan and overseas
- 4. Medical Support Business: Opening and operation of clinical malls; support of provision of better medical environments
- Contract Research Organizations partially conduct and support tasks of clinical trials for a drug or a 2 medical device for pharmaceutical companies and other institutions

In addition to providing regenerative medicine and gene therapy drug discovery technologies, the Advanced Medicinal Treatment Business has four self-developed pipelines, which may expand sales significantly once products are approved. I'rom Group is expected to increase corporate value over the long term, thanks to its hard-toimitate competitive advantages in responding to advanced medical needs, such as regenerative medicines, market for which is projected to increase by 28%<sup>3</sup> per year.

The regenerative medicine market's annual growth projection (2020-2030) by the Ministry of Economy, Trade and Industry

#### Corporate value structure aiming for high growth, by capturing market growth potential, 28% per year

Comprehensive power



A dramatic growth is projected in the advanced medicine and regenerative medicine market

Enhanced capacity to support clinical development of new therapies and new advanced medicinal products

### Comprehensive capacity to support development process in the market which is expected to grow by 28% per year

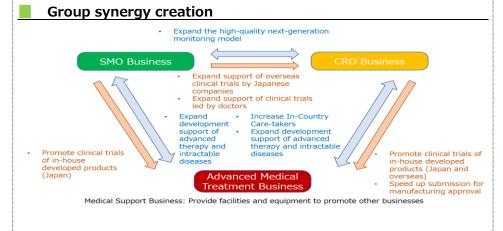
Dramatic growth is projected in the advanced medicine and regenerative medicine market. According to the Ministry of Economy, Trade and Industry, the global regenerative medicine market is estimated to grow by 28% per year from 2020 to 2030 to \$12 trillion and further to \$30 trillion by 2050. In this market, development process of new drugs and new medical technologies is particularly important and requires companies concerned to have comprehensive capacity to support increasingly complex, large-scale, global development processes. I'rom Group's four businesses support these high-growth advanced medicinal development processes, enabling the company to target benefit from the 28% expected growth in this market.

# Unique positioning and competitive advantages

# Hard-to-imitate combination of a domestic leading SMO, a global CRO, and the advanced medicinal treatment business

I'rom Group has combined knowhow and networks that have been formed and accumulated in its business areas and has raised capacity to support clinical development of new therapies and new advanced medicinal products. Its business domain is broad based, ranging from Australia's CRO business to its subsidiary's R&D in regenerative medicine and gene therapeutic preparations, while being positioned as a leading SMO player and the industry's pioneer.

I'rom Group's clinical trial knowhow and networks with medical institutions, that have been accumulated in the SMO and CRO Businesses, are utilized in R&D of gene therapeutic preparations in the Advanced Medicinal Treatment Business. At the same time, the latter business' networks with universities and research institutes are expected to contribute to expansion in the former businesses. Moreover, the Medical Support Business supports the entire group's smooth business operation by establishing and providing facilities for other businesses.



(Source) Prepared by J-Phoenix Research based on I'rom Group's materials and interviews

## Logics of group synergies Double impacts from greater cash generation and speedy development

The synergies described above are summarized below from a perspective of shareholders, with a focus on the relationship between the SMO and CRO Businesses and the Advanced Medicinal Treatment Business. Synergies between both businesses raise cash generating power of the former and accelerate development speed of the latter, creating a virtuous cycle. As a result, I'rom Group's competitiveness in a broad-based medical field is enhanced and is expected to realize a very high growth rate, partly being

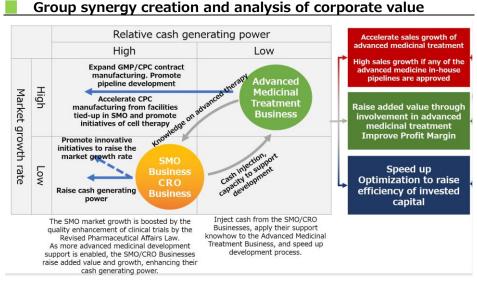
Double impacts from greater cash generation and speedy development

Expand areas to support clinical trials and increase added value by coordination among business units

Towards outstanding growth in and after fiscal year 2019

# boosted by a high growth in the advanced medical market.

I'rom Group is realizing an ideal portfolio in which investment in advanced medicinal treatment is financed by stable cash flow from SMO and CRO businesses. Medical support services also play an important role in terms of stable cash flow.

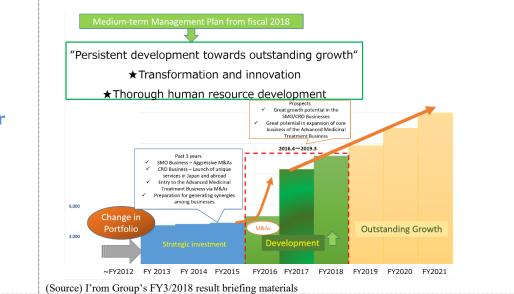


(Source) Prepared by J-Phoenix Research based on I'rom Group's FY3/2018 result briefing materials and interviews

#### Planned focus areas and medium-term outlook

In the SMO Business, a conventional mainstay business, I'rom Group will focus on expanding areas to support clinical trials and increasing added value by coordinating with the Advanced Medicinal Treatment Business and the CRO Business. In the Advanced Medicinal Treatment Business, where I'rom Group has invested heavily in recent years, the company plans (1) to increase manufacturing contracts and operate manufacturing facilities at their full capacity; (2) to expand pipelines for gene therapy and cell therapy and accelerate clinical trial operations; and (3) to try to make its core technologies a de-facto standard in Japan and overseas through proactive out-licensing. By taking these initiatives of its medium-term management plan, I'rom Group aims for persistent development towards outstanding growth.

#### Growth path from fiscal year 2019 (conceptualization)



# 2. Corporate profile and history

Corporate nai	me	I'rom Group Co., Ltd.		
Established		April 9, 1997		
President & CEO		Toyotaka Mori		
Headquarters		Iidabashi Grand Bloom, 2-10-2 Fujimi, Chiyoda-ku, Tokyo		
Capital				
-	Fiscal year end March			
	exchange listing The First Section of the Tokyo Stock Exchange [2372]			
	er of employees 666 (as of March 31, 2018)			
(Source) Prepare	d by J-Phoenix Rese	arch based on company materials		
Corpor	rate organiza	ation		
		Provide regenerative medicine and gene	ID Pharma Co., Ltd.	
		Trovide regenerative inculaine and gene	I'rom Co., Ltd.	
		SMO Services: Support medical institutions	Ethic Co., Ltd.	
		which conduct clinical trials	I'rom CS Co., Ltd.	
I'rom (	Group		I'rom NA Co., Ltd.	
Co., 1	Ltd.		MC Fields Co., Ltd.	
		CRO Services: Support clinical trialas	I'cros Co., Ltd.	
		conducted by pharmaceutical companies in	I'cros Japan Co., Ltd.	
		Japan and overseas	CMAX Clinical Research Pty Ltd	
		Medical Support Business: Establish and	I'rom PM Co., Ltd.	
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# 3. M&A-driven business expansion

# Aggressive in M&As

# Aggressive in M&As to build an organization engaged in every process in clinical development

Since 2013, I'rom Group has been aggressive in M&A activities, aiming to be involved in all processes of developing new drugs and new medical technologies. Specifically, I'rom Group has established a unique business model by strengthening alliances with core hospitals, expanding its clinical trial network in Japan and overseas through M&A, and making DNAVEC (currently ID Pharma), which possesses advanced medical technologies, a fully-owned subsidiary. As a result, I'rom Group's business portfolio now has four business units. The company's major acquisitions since 2013 have been summarized below from four perspectives, sales growth, profitability, invested capital, and business risks. It has pursued growth in both sales and profit and has concurrently given great attention to controlling both efficiency in invested capital and business risks associated with business growth, as strategy for stable business expansion.

#### Advanced Medicinal Treatment Business

# Expansion of business fields in cell/regenerative medicine and gene drug discovery

Expansion of business fields in cell/regenerative medicine and gene drug discovery

Enhanced tie-ups with domestic partnering medical institutions, advanced specialized medical institutions, and CROs

Acquisitio	n of DNAVEC Corporation (currently ID Pharma): January 2014
Sales growth	Expansion of business fields in cell/regenerative medicine and gene drug discovery by connecting advanced regenerative medicine technology with a network of medical institutions
Profita- bility	Development of new therapeutic treatment, such as a breakthrough in treating intractable diseases, have the potential of generating high profit.
Invested capital	Promoting sales of products that use Sendai virus vector (SeV), a core technology. Clinical studies of advanced treatment methods may raise the efficiency in invested capital.
Business risks	Dissolution of patent licensee contracts; disadvantageous renewal of contracts; and product liability risks for pharmaceutical and bio-related products

(Source) Prepared by J-Phoenix Research based on company materials and interviews

#### SMO (Site Management Organization) Business

Enhanced tie-ups with domestic partnering medical

institutions, advanced specialized medical institutions, and

#### **CRO** companies

Acquisition of Clinical Support Company (currently I'rom CS): March 2013

Acquisition of MC Fields Co., Ltd.: October 2013

#### Establishment of I'rom NA (joint venture): May 2016

Sales growth	An expanded network in the SMO Business (services for institutions implementing clinical trials) is likely to lead to expanded tie-ups with medical institutions and to contracts for clinical trials in new fields
Profita-	Raise efficiency due to economies of scale and coverage
bility	
Invested capital	Raise capital efficiency due to economies of scale in tie-ups with domestic partnering medical institutions and advanced specialized medical institutions
Business risks	Shrinkage of clinical trial scales in Japan, caused by increase in international joint development; decline in clinical trials for lifestyle-related diseases

(Source) Prepared by J-Phoenix Research based on company materials and interviews

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#### Enhanced added value in services in coordination with CRCs

#### Acquisition of Ethic Co., Ltd.: June 2017

Sales	Expansion of shares in SMO Services and enhancement of the clinical trial network
growth	
Profita-	Enhanced added value in services in coordination with Ethic's experience with CRCs.
bility	Consolidation of indirect departments.
Invested	Raise capital efficiency by expanding a network including medical institutions in the Kanto,
capital	Koshin-etsu, and Chubu Regions and by expanding clinical trials for kidney diseases
	treatment.
Business	Shrinkage of clinical trial scales in Japan, caused by increase in international joint
risk	development; decline in clinical trials for lifestyle-related diseases

(Source) Prepared by J-Phoenix Research based on company materials and interviews

### **CRO Business**

#### Acquisition of CMAX Clinical Research Pty Ltd.: December 2016

Sales growth	Overseas expansion is expected to lead to sales growth.
Profita- bility	Development of overseas CRO services, building of relationships with global companies engaged in regenerative medicine, and information gathering on projects of GMP vector manufacturing facilities are expected to raise profitability.
Invested capital	Raise capital efficiency by supporting Japanese companies' overseas expansion in the clinical trial business and by global development in cooperation with leading research units of pharmaceutical companies in Asia and Oceania.
Business risk	Impacts of revisions in drug legislation on development, manufacturing and sales; impacts from discontinuation and suspension of clinical trials
(Source) Prep	pared by J-Phoenix Research based on company materials and interviews

# 4. Mission, vision, offered value, and business model

Moving forward with the goal of building tomorrow's healthcare

Offered value is to provide one-stop service that meets customers' needs, by broadly covering every process of clinical development.

### Mission

With the corporate philosophy "Moving forward with the goal of building tomorrow's healthcare," I'rom Group has consistently strived since its foundation to achieve the objective of contributing to medical development to elevate the quality of patients' lives. I'rom Group continues to be dedicated to making further efforts to provide support for clinical trials and for technological development of advanced medicinal treatment, enabling patients to use the latest medicine with ease, and as soon as possible.

#### Vision

I'rom Group operates four business units; Advanced Medicinal Treatment Services, SMO Services, CRO Services, and Medical Support Services. Through these operations, I'rom Group uses its comprehensive capability in providing services that are needed in support of clinical development processes, seeks to differentiate its services, and establishes competitive advantages that are difficult to imitate. I'rom Group intends to be involved in all processes of new medical technologies and drug development and to obtain overwhelming competitiveness in the regenerative medicine market that is growing by 20-30% per year.

#### I'rom's value for its customers

The value that I'rom Group uniquely offers is to provide one-stop service that meets customers' needs, by broadly covering every process of clinical development. Initially, after the company was formed, it was only engaged in the SMO Business, supporting medical institutions conducting clinical trials. It then started its CRO Business for pharmaceutical companies. Moreover, it started the Advanced Medicinal Treatment Business to do its own R&D activities and began the Medical Support Business to operate clinics in malls, or "clinic malls" (akin to multiplex theaters) leading to establishment of a unique business portfolio that generates high synergies. Insights and network of each business unit can be utilized in other business units, allowing I'rom Group to tailor services that fulfill more complicated needs of customers. I'rom Group's most significant value is to facilitate patients use of the latest medical treatment with ease, and as soon as possible, with its comprehensive capability in the four business units of Advanced Medicinal Treatment, SMO, CRO, and Medical Support Services.

#### Mission, vision, and offered value

Mission Moving forward with the goal of building tomorrow's healthcare' Vision Fulfill services required to support clinical development processes in advanced medicine Advanced Medicinal Treatment ② SMO ③ CRO ④Medical Support Capacity to respond to needs evaluating Comprehensive strength of the Comprehensive power Technologies four business units **Fotal Power** training and ev capacity On-site support power "Moving forward with the goal of building tomorrow's healthcare" Quality Ĥ Speed Establish hard-to-imitate competitive advantages (Source) Prepared by J-Phoenix Research based on I'rom Group's FY3/2018 result briefing materials and interviews

Providing services needed to support advanced medicine's clinical development processes

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Development of drugs and medical technologies using gene therapy and regenerative medicine

R&D capacity centered around its vector technology and technology to induce gene to vector

Strong support for clinical development, including trials for new drugs, mainly in Japan and Australia

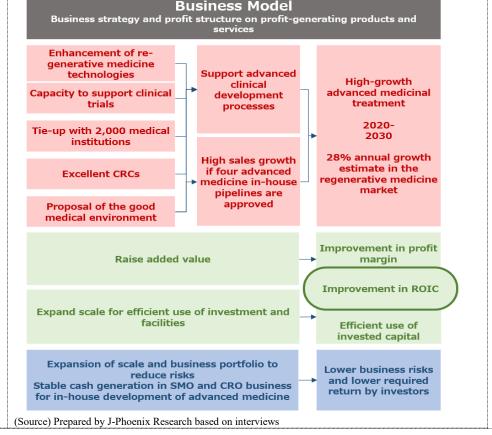
#### Business model

#### I'rom Group's competitive advantages

The medical industry is making amazing progress globally in the development of therapeutic technologies. Along with technology development, pharmaceutical companies' focus of development is shifting from lifestyle-related diseases to areas of diseases with high unmet medical needs, such as cancer and disorders of the central nervous system.

Gene therapy and regenerative medicine are receiving more attention as innovative treatment methods for these intractable diseases. These methods are promising as basic remedy for diseases that have been difficult to treat and diseases that have no known cure but only result in treatment of symptoms. They may also alleviate the burden borne by patients' long-term medication, hospital stay, and other factors – and thus can lead to improving the quality of their lives.

I'rom Group is developing drugs and medical technologies using gene therapy and regenerative medicine, by utilizing its R&D capacity centered around its vector technology and technology to induce genes to a vector. I'rom Group also provides its outstanding technology to pharmaceutical companies and research institutes worldwide through product supply and contracted manufacturing, thereby encouraging commercialization of gene therapy and regenerative medicine. Regarding support for clinical development, including the clinical trials which are indispensable for new drug development, I'rom Group is concentrating heavily on activities in Japan and Australia, striving to embody the enhanced technology and knowledge needed to cope with changing needs in diverse efforts at drug development.



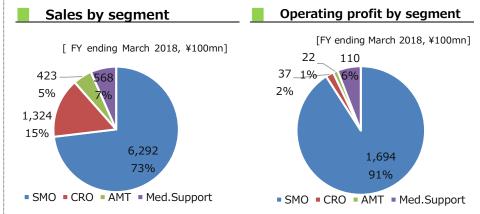
#### I'rom Group's business model

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Outstanding	One of I'rom Group's strengths lies in its comprehensive capability generated by		
technologies and	synergies among its business units. It has outstanding technologies and R&D		
R&D capability	capability that contribute to clinical applications, as well as many experienced staff		
that contribute to clinical	who support advanced clinical trials. Dedicated to the corporate philosophy		
applications	"Moving forward with the goal of building tomorrow's healthcare," I'rom Group is		
applications	contributing to development of new medical technologies and drugs, to elevate the		
	quality of patients' lives.		
Many experienced	Specifically, I'rom Group is taking the following strategic initiatives to enhance		
staff who support	competitiveness.		
advanced clinical	1. Expand business fields, centered around gene drug development, cells and		
trials	regenerative medicine, and contract manufacturing, by using core		
	technologies (i.e., Sendai virus vectors) of subsidiary ID Pharma;		
	2. Expand the SMO Business by coping with the revised GCP and		
Expand business	supporting clinical trial quality improvement of medical institutions;		
of the SMO	3. Broadly engage in clinical development pipelines through its four business		
services by coping	units and generate synergies among the units; and		
with the revised	4. Establish a broad-based network in Japan and overseas through		
GCP and	aggressive business alliances and out-licensing deals.		
supporting clinical	By taking these initiatives, I'rom Group intends to support the process of developing		
trial quality improvement of	advanced medicinal treatment and launch its own advanced medicine pipeline, with		
medical	the ultimate aim of helping more patients to benefit from the latest medical		
institutions	treatment, a field which is expected to achieve the high annual growth of 28%,		
	backed by advances in regenerative medicine and other areas. In addition, I'rom		
	plans to realize sustainable high growth with a contribution from expansion in its		
	core SMO Business by supporting clinical trial quality improvement of medical		
	institutions in their response to the revised GCP.		
	At the same time, I'rom Group is determined to raise its added value, improve capital		
	efficiency, and reduce business risks. Consequently, the company intends to raise its		
	corporate value and shareholder value.		

# 5. Business segments

Deliver the latest drugs to patients as quickly as possible Under a corporate philosophy "Moving forward with the goal of building tomorrow's healthcare," I'rom Group is comprehensively engaged in four business units (Advanced Medicinal Treatment Services, SMO Services, CRO Services, and Medical Support Services) in order to deliver the latest drugs to patients as quickly as possible.



# Pioneer of SMO services in Japan

(Source) Prepared by J-Phoenix Research based on I'rom Group's FY3/2018 result briefing materials

#### SMO Business

SMO (Site Management Organization) means an organization which assists clinical trial facilities. For a candidate drug to be approved for use, clinical trials to determine its safety and efficacy are mandatory. A medical institution that conducts a clinical trial must handle diverse task, including management of the data collected and diverse types of documents, in addition to clinical examination and testing. I'rom Group's SMO Business support specialized work that medical institutions must undertake when clinical areas are conducted.

Since its beginning, I'rom Group, a pioneer of SMO in Japan, has expanded its integrated internal support organization, from early-phase clinical trials to post-marketing clinical trials mainly for new drugs. The entire group is also engaged in quality enhancement of clinical research coordinators (CRC) and improvement of management structure.

Moreover, beyond its support activities, the company has expanded into advanced specialized fields, such as clinical studies, epidemiological study, and has promoted alliances with university hospitals and core hospitals.

The revised GCP requires medical institutions to improve the quality of clinical trials. I'rom Group therefore believes that it can expand business in the so-called low-growth SMO market by supporting quality management and process building that matches the actual conditions of medical institutions.

Proactive support, from clinical studies and epidemiological study to promotion of alliances with university hospitals and core hospitals

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CRO Services provide unique services, using know-how accumulated in the SMO Services

Acquired CMAX, a pioneer in clinical trial services in Australia

#### **CRO Business**

CROs (Contract Research Organizations) undertake subcontract work or provide assistance concerning clinical trials at the development stage of drugs and medical devices and post-marketing clinical trials. I'rom Group's CRO Business provide services for this, using know-how accumulated in the SMO Business.

I'rom Group acquired shares of CMAX, a pioneer in clinical trial services in Australia, in December 2016, and then made it a fully-owned subsidiary in August 2017. CMAX is experienced in supporting early-phase clinical trials, including First-In-Human (FIH) trials, in which global large-scale clinical trials or trial drugs are applied to human beings for the first time in the world. Having CMAX in the Group is expected to contribute to quality enhancement and business development of I'rom Group's SMO and CRO Businesses.

### Advanced Medicinal Treatment Business

Engaged in services of regenerative medicines and gene drug discovery, based on vector technology

Support for newlyopened medical institutions, such as by introducing clinical trial opportunities In order to overcome intractable diseases, advanced medical technologies, including regenerative medicines and gene drug discovery, are much desired, as are next-generation medical technologies and drug discoveries. Within the Group, ID Pharma is promoting advanced medicinal treatment services. Based on its vector technology, ID Pharma is engaged in services related to regenerative medicine and gene drug discovery. The company has world top-class technology in vector development and manufacturing, including the Sendai virus vector, and is highly regarded in the bio industry. In recent years particularly, it has been engaged in regenerative medicine work, such as iPS cell production technology, and gene drug discovery services, including gene medicines and vaccines.

#### Medical Support Business

I'rom PM is a group company that makes proposals based on the medical environment to reduce patients' burden of making hospital visits, by opening and operating clinic malls (multiplex medical facilities with clinics of different specialties located on the same floor). In addition, I'rom PM assists doctors to open their clinics in a clinic mall and introduces clinical trial opportunities to medical institutions, supporting their management from many aspects.

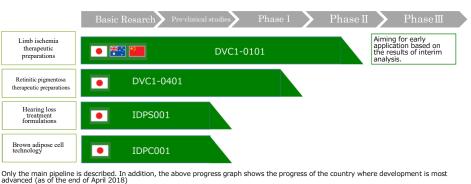
# 6. Internally-developed advanced drugs and medicinal treatment

Trend of advanced drugs and medicinal treatment under development by I'rom Group

Limb ischemia therapeutic preparations

Roughly 0.4 million patients in Japan, 3 million in the US and Europe, and 6.5 million in China This section explains the trend of advanced drugs and medicinal treatment under development by I'rom Group. The development process starts from basic studies of a new drug, then to pre-clinical testing by use of animals and in-vitro methods with cells to confirm the efficacy and safety of the drug, and to clinical trials with humans. After being approved by authorities, the drug can be manufactured and sold.

#### Major pipeline progress status



(Source) I'rom Group's FY3/2018 result briefing materials

#### Limb ischemia therapeutic preparations DVC1-0101

#### Target disorder

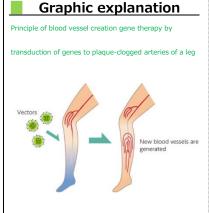
Ischemic limb results from impaired blood flow caused by narrowing of the lumen of the blood vessels to the lower limbs due to factors such as arteriosclerosis. This causes pain in the lower limbs, walking difficulty and eventually ulceration and necrosis, and in severe cases leads to lower limb amputation.

#### Market size

The number of patients is estimated to be about 0.4 million in Japan, 3 million in the US and Europe, and 6.5 million in China.

#### Development schedule

During a clinical trial, DVC1-0101 was administered to the first patient in November 2016. I'rom Group plans to apply for approval of early-phase manufacturing, based on the interim analysis, within 2019, and aims at receiving conditional early approval.



New blood vessels by transduction of genes

(Source) I'rom Group's website

Target disorder

### Retinitis pigmentosa therapeutic preparations

## At least 30,000 patients in Japan and 2 million worldwide are estimated

### Retinitis pigmentosa therapeutic preparations DVC1-0401

#### Market size

Retinitis pigmentosa is a genetic disorder of the eyes where there is gradual loss of photoreceptor cells of the retina. The disorder tends to emerge from early adulthood with later possibility of loss of vision. Mutations in approximately 50 kinds of genes have already been identified as causes but there is no effective cure at present. It is designated as an intractable disease by the Ministry of Health, Labour and Welfare.

Approximately one in 5,000 individuals is said to experience this disease. The number of patients is estimated to be at least 30,000 in Japan and 2 million worldwide.

#### **Development schedule**

Phase I and IIa clinical trial is under way at Kyushu University Hospital and to date no safety issues have arisen. In China, DVC1-0401 has been out-SoloBio licensed Beiiing to Genetechnology Company Ltd.

#### Efficacy shown in the pre-clinical trials

Images on the right show effects of DVC1-0401 administered to model rats that have retinitis pigmentosa. Without treatment, nerve cells become degenerated but after treatment,

Efficacy of I'rom Group's gene therapeutic products in preventing shrinkage of nerve cells of model rats with retinitis pigmentosa B C D F A BSS (7W) (5W) (7W) SIV-Not treated

degeneration appears to be prevented.

#### (Source) ID Pharma's website

### Hearing loss treatment formulations IDPS001

(3W)

Target disorder Neural hearing loss, a target disorder for this drug, is triggered by some trouble between the inner ear and the hearing nerve. As the sound is not well handled in the inner ear and the nerve to transmit the sound's electric signal into the brain does not function well, the content of the sounds transmitted is vague and unclear. Sudden hearing loss is also categorized as being in this type and a cure has yet to be found.

#### Market size

With differences from one individual to another, hearing loss accompanying aging occurs widely. There is a huge market in Japan and overseas.

#### **Development schedule**

I'rom Group's joint research with the National Defense Medical College resulted in establishing a gene administration method in August 2016. At present, preclinical trials that use animals and cell culturing are being conducted to determine efficacy and safety of the drug.

**Therapeutic** products for hearing loss

A huge market in Japan and overseas

PEDG (7W)

# Brown adipose cell technology

Direct transplant to humans and potential for wider applications, including drug screening and basic research

## Highlighted as a drug discovery target for metabolic syndrome

### Brown adipose cell technology IDPC001

# Significance of the technology

Brown adipose cells produced with this technology can be directly transplanted to humans as a regenerative medicine product for obesity and metabolic syndrome. In addition, it is expected to be widely adopted for drug screening, basic research, and other purposes.

#### **Development schedule** It is currently at a basic study phase, but I'rom Group has already obtained patents in Japan, the US, Australia, and China and is promoting technology development toward commercialization.

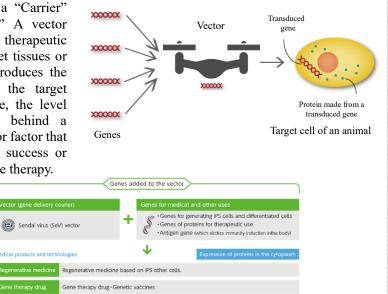
What is brown adipose cells? Brown adipose cells or brown fat cells are one of the two adipose cells found in mammals. While the white fat cells mainly store excess energy as adipose, the brown fat cells dissolve adipose and generate heat. Human adults have brown fat cells in the neck, upper part of clavicle, fusion sagittal, and para-spine part of the body but its quantity is gradually reduced along with aging. Animal trials have proved that brown fat cells are effective in preventing obesity and improving metabolism. Inverse correlation between a decline in brown fat cells and the development of a metabolic disorder has evidenced also been in humans. highlighting the importance of brown fat cells as a drug discovery target to develop medicine for metabolic syndrome.

# Sendai virus vector to become de-facto standard

Sendai virus vector, developed by ID Pharma, a subsidiary of I'rom Group, has proven to have properties to accomplish something existing vectors cannot do in terms of safety and efficacy and is regarded as one of the world standard vectors.

Sendai virus vector to become defacto standard

A vector's technological quality is an important condition for successful gene therapy and regenerative medicine What is a vector? Vector means a "Carrier" or "Conveyer." A vector transports a therapeutic gene(s) to target tissues or organs and introduces the gene (s) into the target cells. Therefore, the level of technology behind a vector is a major factor that determines the success or failure of a gene therapy.



(Source) Prepared by J-Phoenix Research based on I'rom Group's website and others

Sendai virus vector, being an RNA virus molecule, is not transported into the nucleus of a cell and without incorporating it into the chromosome (in principle)

# High safety to constrains cancer risk without affecting the chromosome

### Advantages of Sendai virus vectors

Vectors commonly used at present include plasmids, retroviruses, lentiviruses, adenoviruses, adeno-associated viruses, and Sendai virus. According to the data published by the Journal of Gene Medicine in 2016, ratios of vectors used in gene therapy in the world are 21.4% for adenoviruses, 18.2% for retroviruses, and 17.2% for plasmids.

#### Comparison of Sendai virus vector with other vectors

Vectors – types	Main Target Diseases	Expression Period of Genes	Gene Introduction Efficiency	Integration into Chromosome	Safety
Non-viral Plasmid	Circulatory Diseases	Short Term	Low	Low Frequency	0
Virus					
Retrovirus	Hereditary Diseases, Cancer	Long Term	Low	Yes	×
Lentivirus	Hereditary Diseases, Cancer	Long Term	Medium	Yes	Δ
Adenovirus	Cancer, Infectious Diseases	Short Term	Medium	Low Frequency	0
Adeno-associated Virus	Hereditary Diseases, Nervous System Disorders, Ocular Diseases, etc.	Long Term	Medium	Low Frequency	0
Sendai Virus	Circulatory Diseases, Infectious Diseases, Cancer, etc.	Mid/Short Term	High	No	O

(Source) I'rom Group's website

While many types of vectors are DNA molecules and are transported inside the nucleus of a cell to express genes, Sendai virus vector, not being an RNA virus molecule, is not transported into the nucleus of a cell and in principle without being incorporated into the chromosome. Sendai virus vector is therefore regarded highly safe as it does not affect the chromosome and thus constrains cancer risks.

In addition, due to higher transduction efficiency of genes, relative to other vectors, it can transmit genes to a wide range of cells, including cells that are difficult for genes to be transported there by other virus vectors.

For actual medical treatment using gene therapeutic products and regenerative medical products that use a vector, stable high-volume production of high-safety, high-quality products is required. Sendai virus vector technology, being superior in safety and efficiency relative to other vectors, can fulfill such a requirement.

Safety and efficiency of vectors are critically important for commercialization of regenerative medicine and gene therapy that use vectors. I'rom Group's Sendai virus vector can be expected to become a world standard in vectors. Many research institutes and companies have accredited its advantages and have been using it in R&D of various disease fields, such as regenerative medicine and gene drug discovery. Continued out-licensing and joint research projects by I'rom Group are expected to lead to higher diffusion of Sendai virus vectors.

#### CytoTune-iPS

CytoTune-iPS is an iPS reprogramming kit that maximally utilizes properties of Sendai virus vectors. By incorporating the four Yamanaka factors, this kit enables lab technicians to efficiently generate iPS cells. Key properties are high efficiency, reduction in cytotoxity, and quick elimination of vectors. With passage of time, the vector and inducing factors are eliminated. ID Pharma has already out-licensed the kit to renowned research institutes and major pharmaceutical companies around the world.





Incorporate the four Yamanaka factors and efficiently generate iPS cells

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Established a supply structure of high-quality vector products for clinical use

### In compliance with GMPs in Japan, the US, and Europe

Realizing multiproduct, multipurpose manufacturing

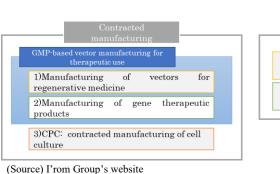
# Start of operating a GMP vector manufacturing facility

In 2016, ID Pharma, a subsidiary of I'rom Group, constructed a GMP (good manufacturing practice) facility for formulating vectors for clinical trials and treatment, and has established a supply structure of high-quality vector products for clinical treatment by utilizing its accumulated knowhow concerning a wide range of vector manufacturing technology. GMPs are the practices required to conform to guidelines concerning manufacturing facilities and their management, as well as management of quality and manufacturing, with the aim of ensuring safety of pharmaceutical products and medical devices. ID Pharma's facility has the following two features:

1. Specifications comply with GMPs in Japan, the US, and Europe: The facility complies with the GMPs in manufacturing sterile products in the three regions, assuming launch of products, such as gene therapeutic products and regenerative medicine products, in the global market.

2. Realization of multi-product, multi-purpose manufacturing: The facility has realized multi-product, multi-purpose manufacturing by having a GMP manufacturing area with special operating rooms for each process, including vector manufacturing, refining, and filling, as well as a cell processing area.

- 1) Manufacture of vectors for regenerative medicine: Vectors for regenerative medicine, including Sendai virus vector, are manufactured on a GMP basis.
- 2) Manufacture of gene therapeutic products: Gene therapeutic products that use vectors, including Sendai virus vector, are manufactured.
- 3) Business development as a cell processing center (CPC): The facility undertakes contracted work in cell culture and processing in regenerative medicine.
- 4) Manufacture of CytoTune®-iPS: Concerning CytoTune®-iPS, an iPS reprogramming kit that is already sold globally for research purposes, vectors for clinical treatment are manufactured and supplied to the global market.
- 5) Manufacture of the company's therapeutic products: Medicine to treat peripheral arterial disease, developed by ID Pharma, and other products are manufactured.



Role of the GMP vector manufacturing facility

d ing ing for vectors for ene therapeutic facturing of cell

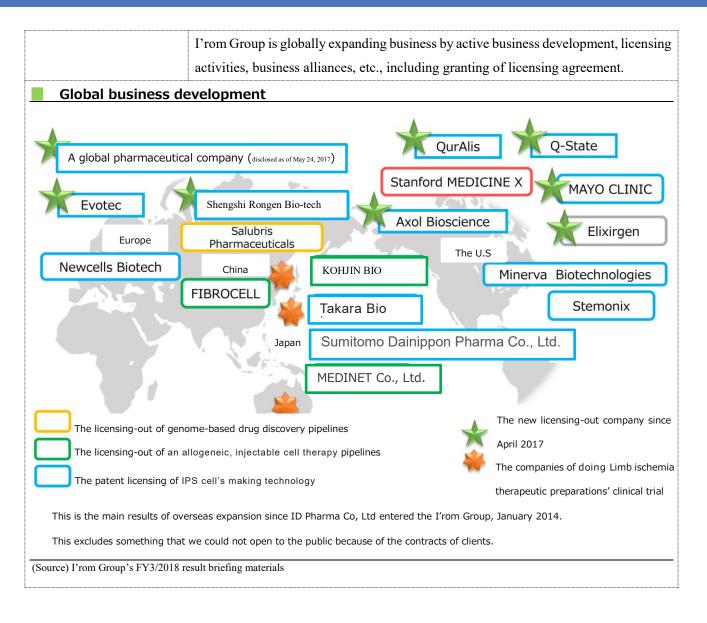
# 7. Licensing agreement status

# Out-licensing to leading research institutes

The out-licensing situation of CytoTune®-iPS and Sendai virus vector is summarized below. I'rom Group is widely out-licensing to major pharmaceutical companies and leading research institutes in the field of advanced medicine. If these licensees make progress in business development, significant impact on I'rom Group's sales can be expected.

Agreer	ment Date	License	Agreement Details
2018	Мау	Dendrix (Japan)	Strategic partnership agreement on use of management resources such as technologies, knowledge, and network of each party and on business development in the advanced medicine field
	Мау	Evotec (Germany)	Agreement to enable to produce iPS cells using CytoTune <sup>®</sup> -iPS and to use differentiated cells derived from these iPS cells for drug-discovery screening, etc.
	April	Shengshi Rongen Bio-tech Company (China)	Agreement to enable to produce iPS cells using Sendai virus vector and to use these iPS cells to develop, manufacture, and sell products for beauty purposes not exclusively in China
	February	QurAlis (USA)	Agreement to enable to produce iPS cells using CytoTune <sup>®</sup> -iPS and to use differentiated cells derived from these iPS cells for drug-discovery screening, etc.
	January	Q-Sate Biosciences, Inc. (USA)	Agreement to enable to produce iPS cells using CytoTune <sup>®</sup> -iPS and to use differentiated cells derived from these iPS cells as research products for research purposes with a specified joint research partner
2017	July	Axol Biosciences, Inc. (USA)	Agreement to enable to produce iPS cells using CytoTune <sup>®</sup> -iPS and to supply and sell differentiated cells derived from these iPS cells as research products
	Мау	A global pharmaceutical company	Agreement to enable to produce iPS cells using Sendai virus vector and to use differentiated cells derived from these iPS cells for drug-discovery screening, etc.
	Мау	Elixirgen, LLC (USA)	Agreement to enable to use Sendai virus vector to incorporate Elixirgen's specific genes and to produce products for use and sales for research purposes
	April	Mayo Clinic (USA)	Agreement to enable to produce iPS cells using CytoTune <sup>®</sup> -iPS and to supply and sell differentiated cells derived from these iPS cells as research products
2016	July	Kohjin Bio (Japan)	Agreement to enable to use ID Pharma's "patent technology for production of dendritic cells" mainly for cancer therapy
	March	StemoniX (USA)	Agreement to enable to produce iPS cells using CytoTune <sup>®</sup> -iPS and to supply and sell differentiated cells derived from these iPS cells as research products
2015	September	Takara Bio (Japan)	Agreement to enable contract manufacturing of iPS cells using CytoTune <sup>®</sup> -iPS for research purposes and to develop, produce, and sell the iPS cells
	August	Newcells Biotech Limited (UK)	Agreement to enable to produce iPS cells using CytoTune <sup>®</sup> -iPS and to supply and sell differentiated cells derived from these iPS cells as products
	August	Minerva Biotechnologies (USA)	Agreement to enable licensee to produce iPS cells using CytoTune <sup>®</sup> -iPS and to supply and sell these iPS cells as products
2014	December	Fibrocell Asia Inc. (China)	Agreement to enable use of ID Pharma's "patented technology for production of dendritic cells" mainly for cancer therapy
	November	KAC (Japan)	Agreement to enable licensee to produce iPS cells using CytoTune <sup>®</sup> -iPS for research purposes and to supply and sell these iPS cells as products
	September	Sumitomo Dainippon Pharma Co., Ltd. (Japan)	Agreement on licensing concerning technology to produce iPS cells for clinical use for human regenerative medicine by a nuclear reprogramming method using Sendai virus vector
	Мау	Medinet Co., Ltd. (Japan)	Licensing agreement of the "patented technology for production of dendritic cells" for use together with the immune cell therapy that Medinet provides, worldwide ex. China
Source)	Prepared by J-Pl	hoenix Research based on company	y materials

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# 8. Market environment and I'rom Group's competition strategy

# High growth in the advanced drugs and medicinal treatment

#### Key trends

- intractable diseases,
- global clinical trials
- gene therapy and regenerative medicine.

## Particularly high growth is expected in the gene therapy and regenerative medicine

#### Outlook of the medical industry

There are three key trends for the future of the industry.

1. Addressing the challenge of intractable diseases

Intractable diseases of unknown etiology with no effective treatment present a major financial and psychological burden. Medical needs for those intractable diseases remain high and research advancement is anticipated.

#### 2. Involvement in global clinical trials

At present 70% of clinical trials in Japan are conducted by global pharmaceutical companies, while smaller Japanese pharmaceutical companies are expected to continue expanding overseas. SMOs and CROs are therefore required to provide one-stop development support for global clinical trials.

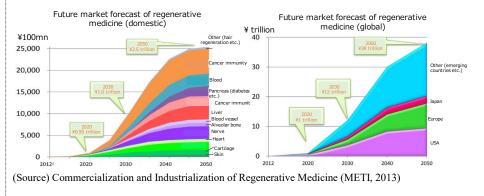
**3.** Full-scale operations for gene therapy and regenerative medicine Gene therapy and regenerative medicine are advanced medical fields where R&D efforts are vigorously carried out. In addition to progress in research, therapeutic technologies are anticipated to be commercialized on a full scale.

I'rom Group's four business units have high growth potential as they can contribute to the above three trends by leveraging their competitive advantages.

Outlook for gene therapy and regenerative medicine

Among potential growth areas in the medical field, noteworthy growth is anticipated in gene therapy and regenerative medicine. According to the Ministry of Economy, Trade and Industry (METI), the regenerative medicine market is estimated to grow from ¥9 billion in 2012 to ¥2.5 trillion in 2050 in Japan and from ¥100 billion to ¥38 trillion in the world (Commercialization and Industrialization of Regenerative Medicine; METI, 2013). I'rom Group is fully prepared to benefit from such growth opportunities, with its management resources and service network.

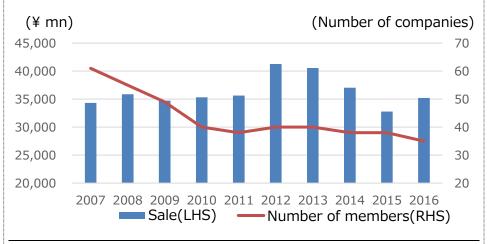
#### Estimates for regenerative medicine



#### The current SMO industry and I'rom Group's strategy

SMO services are basic to I'rom Group since it was established. However, Japan's SMO industry has been entering a mature stage in recent years as overseas clinical trials are increasing. According to the Japan Association of Site Management Organizations (JASMO), SMO sales of its member companies peaked at  $\pm$ 41,279 million in 2012 and gradually declined to  $\pm$ 35,214 million in 2016. Partly due to consolidation in this maturing market, the number of member companies is also on a consistent downward trend, from 61 in 2007 to 35 in 2016.

The sluggish market prompted a change from only targeting small clinics and encouraged alliances with university hospitals and specialized medical centers



#### Japan's SMO market (JASMO member company base)

(Source) Prepared by I'rom Group from JASMO's data for 2015 and 2016 In such an environment, I'rom Group's SMO Business recorded operating losses from fiscal 2013 to fiscal 2015. The company officially started SMO services in early 2000's when a major part of new drug development was for hyperlipidemia and other lifestyle-related diseases and clinical trials were mainly conducted in small-scale medical institutions that collected subjects more easily than large hospitals, the previous main institutions for trials. As smaller clinics lacked trial experience as well as infrastructure and staff needed for trials, there was an increase in demand in SMOs to support clinical trials.

However, moving on to the late 2000's, a mainstay of new drug development has shifted from lifestyle-related diseases to anticancer drugs and the locus of trials has been shifting to large hospitals. The resulting decline in support services at small clinics is a background for sluggish sales of the SMO industry in recent years.

Given a shift in trial locations to large hospitals, I'rom Group changed its strategy of targeting only small-scale clinics and began forming alliances with university hospitals and specialized medical centers. Thanks to this new strategy, I'rom Group has turned to generate operating profit by raising the ratio of sales in advanced specialized medical fields, including cancer and intractable diseases, to large-scale medical institutions.

## Established a leading position in the industry, thanks to a change in strategy

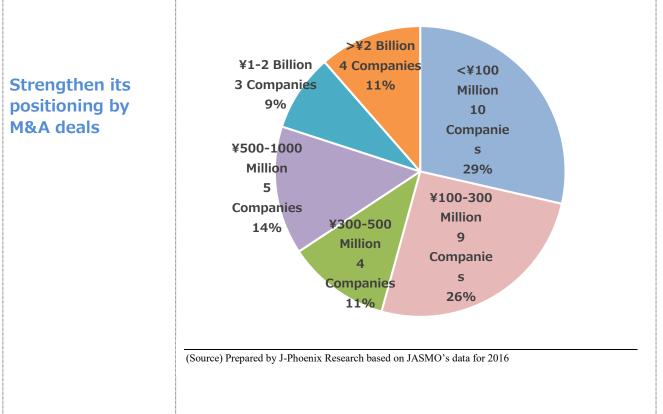
Challenges and future initiatives
 I'rom Group is promoting the following three strategies in the maturing SMO industry.
 Enhance the one-stop support capability of performing clinical trials by generating synergies with its other business units. In particular, it will make strategic proposals to maximize benefits to client companies and patients. This

Making strategic proposals to maximize benefits to client companies and patients, called "high-quality next-generationtype monitoring model." strategic proposals to maximize benefits to client companies and patients. This is called a "high-quality next-generation-type monitoring model."
Expand its network and bring in synergies by pursuing capital alliances or acquisitions with competitors which have business with core hospitals or with pharmacological facilities, as needed.

 Raise value and competitive advantages of not only the SMO Business but also the CRO Business, Advanced Medicinal Treatment Business, and the entire group by promoting alliance with external companies such as AI companies.

SMOs in Japan tend to be small in sales. Among the 35 JASMO member companies, 10 have sales of less than ¥100 million, 9 have sales of ¥100 million -300 million, and only 4, including I'rom Group, have sales of ¥2 billion or more. While companies specialized only in SMO services are struggling, I'rom Group can achieve more synergies by making M&As and expanding its network.

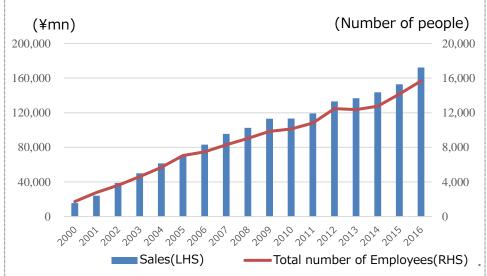




### Japan's CRO market is becoming more competitive with entry of overseas CROs

#### The current CRO industry and I'rom Group's strategy

Contrary to the maturing domestic SMO industry, the CRO industry is expected to have growth potential. According to the Japan CRO Association (JCROA), member companies' CRO sales and number of employees have been growing by about 15% per year on average since 2000 and the trend of outsourcing by pharmaceutical companies is expected to be sustained. At the same time, however, overseas CROs are entering the Japanese market and competition is intensifying.



#### Japan's CRO market (JCROA member companies base)

(Source) Prepared by J-Phoenix Research based on JCROA's annual reports, from 2001 to 2016

Acquisition in Australia to promote global CRO and strengthen competitive advantages In August 2017 I'rom Group made CMAX Clinical Research Pty Ltd., a clinical research center in Australia, a wholly-owned subsidiary. This has enabled I'rom Group to plan and conduct clinical trials in Japan and Australia. CMAX supports all phases of clinical trials, with focus on early-phase trials including First-In-Human (FIH) trials and has extensive experience and knowhow. I'rom Group will incorporate CMAX's knowledges and technologies, and mutually use their networks to enhance its one-stop development support capability from Japanese, Asian, and global perspectives.

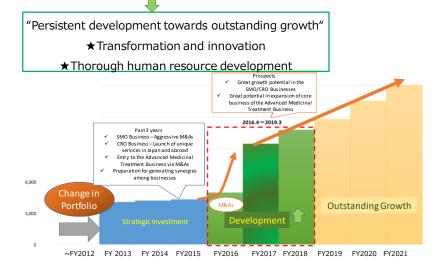
# 9. Medium-term management plan

Towards Outstanding Growth in and after fiscal year 2019 Strategic initiatives

The corporate philosophy "Moving forward with the goal of building tomorrow's healthcare" is expressed in the medium-term management plan by a focus on (1) transformation and innovation and (2) thorough human resource development. The plan identifies fiscal 2018 as a year to "Persistent development towards outstanding growth toward a giant step forward."



Transformation, as well as thorough human resource development for forward-looking evolution



(Source) I'rom Group's FY3/2018 result briefing materials

In the SMO Business, I'rom Group will actively explore the domestic market, where it is already a leading player, and transform itself so as to become a CRC-CRA hybrid comprehensive clinical development support company, one derived from SMO. (CRA stands for Clinical Research Associate, also called a clinical monitor.) In the CRO Business, I'rom Group will position itself as an advanced CRO, one that is a "next-generation monitoring model." Particularly, the company will strive to become a CRO servicing the advanced medicinal treatment segment.

In the Advanced Medicinal Treatment Business, I'rom Group will promote outlicensing in Japan and overseas and take up the challenge of making its core technology a de-facto standard, with the goal of expanding contract manufacturing and making full use of its facilities.

#### Impact on the corporate value structure

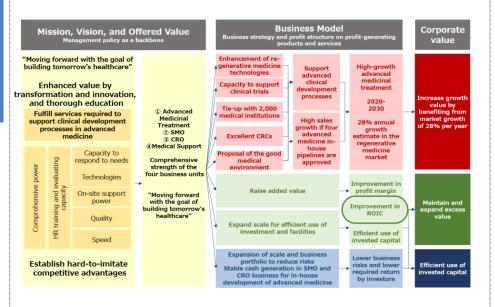
By implementing the medium-term management plan, I'rom Group targets annual sales growth of 10% and an operating margin of 10% or higher.

Transform into a CRC-CRA hybrid comprehensive clinical development support company derived from SMO

# **10.** Corporate value structure from the viewpoint of EVA<sup>®</sup>

High growthoriented corporate value structure I'rom Group's corporate value structure can be described as follows.

#### Structure of corporate value



(Source) Prepared by J-Phoenix Research based on I'rom Group's FY3/2018 result briefing materials and interviews

In approaching the subject of raising corporate value, it is valid to organize efforts according to the following four factors:

- 1) Achieving high sales growth
- 2) Achieving high profit margin
- 3) Capturing higher sales with less use of capital
- 4) Reducing business risks

By combining 2) and 3), it can be alternatively stated as "achieving high profit with less capital."

The measurement method for each factor is as follows:

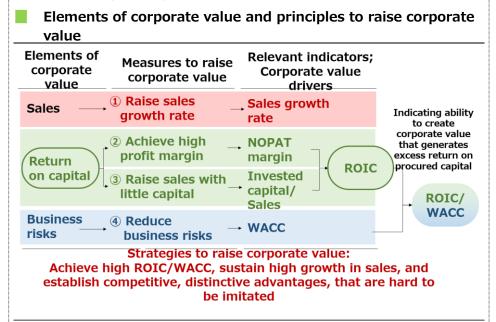
- 1) Sales Growth Rate
- 2) NOPAT (Net Operating Profit After Tax) margin
- 3) Ratio of Invested Capital to Sales
- 4) WACC (Weighted Average Cost of Capital)

ROIC (Return on Invested Capital) is calculated by dividing 2) by 3), to see profitability of Invested capital. ROIC divided by WACC indicates the corporate

Organize a corporate value structure from four perspectives

26/36

value creating ability that generates excess return on raised capital. To raise corporate value, it is imperative to be distinctive, become hard to imitate, and have competitive advantages, which allow the company to achieve higher ROIC/WACC and sustain stronger sales growth.



(Source) Prepared by J-Phoenix Research

I'rom Group's structure of corporate value, based on its own FY3/2019 forecasts, is summarized below.

#### I'rom Group's corporate value factors

Corporate value drivers	Fiscal 2018 plans	Outlook	
Annual sales growth rate	Approx. <b>33.4</b> %	Broadly engage in new therapeutic development and expect 28% growth rate p.a., similar to regenerative medicine market growth	
NOPAT margin <sup>1</sup> (A)	Approx. <b>7.2</b> %	Expect to raise margin, with the aim to exceed 10% due to higher added value and pursuit of synergies	
ROIC (A/B)	Approx. <b>12.5</b> %	Expect to expand. Possibly exceed 20%	Improve ROIC/
Invested capital/Sales <sup>2</sup> (B)	Approx. 57.6%	Expect to decline due to economies of scale	WACC
WACC <sup>3</sup>	Approx. <b>7.0</b> %	Expected to decline due to economies of scale and more stable business base	
¥165.2 billion; Invested capital/Sales = F Invested capital/Sales = Invested capital/ 3. Calculation incorporates the followings: V	Total assets – Cash & deposits ex. iscal 2018 company's sales forecas Sales forecast of ¥920.0 billion for /ACC = After-tax cost of debt × D/i		ebts, Cost of capital = Risk

ичетанетраных premium; p= Covariance (the Company and listed peers vs. FOPIX daily returns)/Variance of TOPIX from May 2013 to May JGBs' 5-year average yield of 0.3% as of Dec. 31, 2017; Risk premium = 5.0-7.0%; the Company's cost of debt, equity/capital structure, etc

(Source) Prepared by J-Phoenix Research

I'rom Group has achieved significant sales growth through M&As. Going forward, high growth of 20-30% per year can be achievable given anticipated growth in

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**Assumption for** corporate value: 20% annual growth over the next 5 years

**Operating margin** can improve to 20%

regenerative medicine and other areas. In addition, if more licensing and launch from the pipeline are realized, its operating margin may improve to about 20% given its business scale. I'rom Group's corporate value may potentially increase significantly, due to higher added value, improvement in capital efficiency from scale merit, and benefit from more stable operation stemmed from expansion in business portfolio.

# A comparable company has a very high operating margin

PeptiDream, listed in the First Section of the Tokyo Stock Exchange (4587), employs a next-generation innovative drug discovery platform with its Peptide Discovery Platform System (PDTS) and can be referenced as a benchmark to estimate I'rom Group's improvement of the operating margin. PeptiDream is used for the discovery and development of hit-candidate drugs, constrained peptides, small molecule, and peptide-drug conjugate therapeutics. The company works in close collaboration with its global and strategic/joint partners, or on its own internal target programs, to identify hit candidates and, depending on the therapeutic area and intended route of administration, develop hit candidates for each target. PeptiDream has many similarities with I'rom Group's strategies as shown below.

	PeptiDream Inc.	I'rom Group
Core strategy	Employ a drug discovery platform and support new drug discovery	Employ staff and technology needed for clinical development and support all development processes of new therapeutic discovery
Alliance strategy	Develop in-house discovery products and promote global alliances	Develop in-house discovery products and promote global alliances
Focus area	Unmet medical needs	Unmet medical needs
Core technology	Flexizyme, an advantageous RNA catalyst to molecule discovery systems, and the Peptide Discovery Platform System (PDTS)	Sendai virus vector, which is advantageous in safety and transduction efficiency, needed for development and manufacturing of gene therapy and regenerative medicine products
Subject substance	Small molecule compounds	Cells

# Similarities in strategy of PeptiDream (4587) and I'rom Group (2372)

(Source) J-Phoenix Research

PeptiDream had a very high operating margin of over 50% in fiscal year ended June 2017. As I'rom Group may also become a platform for advanced medicine

development, it can also be expected to generate high operating margin once that strategy is materialized.

					(Million yen)
Ranking	Securities code	Company name	Sales	Operating profit	Operating margin
1	4587	PeptiDream Inc.	4,895	2,490	50.9%
2	4507	Shionogi & Co., Ltd.	344,667	115,219	33.4%
3	4517	Biofermin Pharmaceutical Co., Ltd.	10,877	3,192	29.3%
4	4521	Kaken Pharmaceutical Co., Ltd.	98,430	27,496	27.9%
5	4528	Ono Pharmaceutical Co., Ltd.	261,836	60,684	23.2%
6	4574	Pharmaceutical Co., Ltd.	9,459	1,857	19.6%
7	4506	Sumitomo Dainippon Pharma Co., Ltd.	466,838	88,173	18.9%
8	4519	Chugai Pharmaceutical Co., Ltd.	534,199	98,934	18.5%
9	4552	JCR Pharmaceutical Co., Ltd.	20,594	3,784	18.4%
10	4530	Hisamitsu Pharmaceutical Co., Ltd.	147,870	26,345	17.8%

#### Ranking in operating margin of pharmaceutical companies

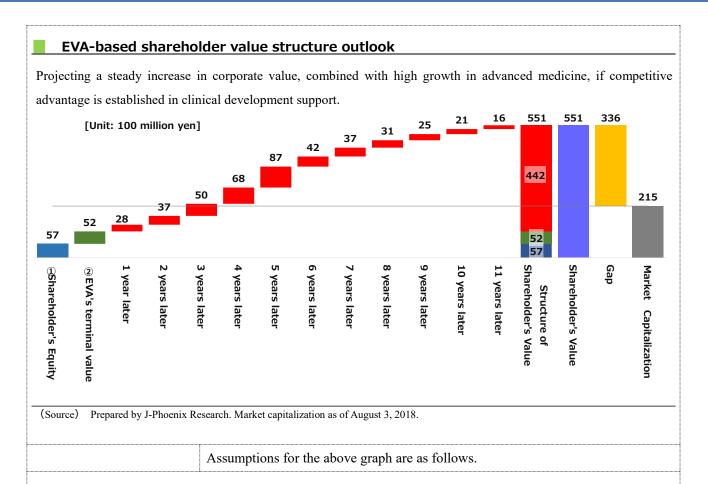
(Source) Prepared by J-Phoenix Research based on full-year results disclosed as of June 2, 2018

While it is extremely difficult to estimate the specific operating margin of I'rom Group, an operating margin of around 20% would not be far-fetched. The company's subject substance of cells is more difficult to handle than PeptiDream's subject substance of small molecule compounds. Therefore, we can even make a case for I'rom Group to achieve a higher margin than PeptiDream.

### Visualizing shareholder value

By using an indicator that combines NOPAT, ROIC, and WACC, I'rom Group can theoretically measure how much excess return is generated each year and how much of that return contributes to raising corporate value. This indicator is EVA (Economic Value Added), a trademark of Stern Steward & Co., calculated by an equation, EVA = NOPAT - Invested Capital X WACC. EVA shows how much cash flow contributes to shareholders' value each year. In the case of I'rom Group, WACC is estimated at around 7%, given its scale, risks of dependence on future growth, and its financial liability position. Based on this WACC figure, EVA can be estimated to be  $\pm 0.36$  billion for fiscal 2018.

Assuming this level is sustained perpetually, EVA's terminal value is  $\pm 5.2$  billion, obtained by dividing EVA of  $\pm 0.36$  billion by WACC. Adding shareholders' equity of  $\pm 5.7$  billion (book value as of March 31, 2018) to  $\pm 5.2$  billion, the sum of  $\pm 10.9$  billion is the shareholder value attributable in fiscal 2018. Use of EVA enables us to visualize how much growth of each year contributes to raising shareholder value. Based on the assumptions (to maintain around 20% sales growth for five years and improve operating margin to 20%) shown in the previous page, shareholder value can be visualized as follows. The estimated shareholder value of about  $\pm 55$  billion is more than double the market cap as of June 12, implying an upside potential of doubling in its stock price.



#### DCF and EVA-based calculation assumptions for shareholder value structure

ncome margin nover ratio invested capital net sales ratio gin + invested capital net sales ratio : created with the original hand of 1 yen) ormer hand) apital	2019.03 115 12.0 10.4% 33.4% 7.2% 57.6% 57.6% 7.0% 12.5% 1.8/F 8.30	138 16.4	2021.03 166 22.4 13.5% 20.0% 9.4% 57.6% 57.6% 7.0% 16.3%	199 30.6 15.4% 20.0% 10.7% 57.6% 57.6% 7.0%	2023.03 238 41.9 17.6% 20.0% 12.1% 57.6% 57.6% 7.0%	2024.03 286 57.2 20.0% 13.8% 57.6% 57.6% 7.0%	2025.03 332 66.4 20.0% 16.0% 13.8% 57.6% 57.6%	2026.03 374 74.9 20.0% 12.8% 13.8% 57.6% 57.6%	2027.03 413 82.6 20.0% 10.2% 13.8% 57.6% 57.6%	447 89.3 20.0% 8.2% 13.8% 57.6%	2029.03 476 95.2 20.0% 6.6% 13.8% 57.6%	501 100.2 20.0% 5.2% 13.8% 57.6%	501 100.2 20.0% 0.0% 13.8% 57.6%	
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# 11. Financial strategy, shareholder return, and ESG

Carefully consider investment balance and financial balance I'rom Group reorganized its business portfolio in 2012, promoted strategic investments from 2013 to 2015, and is focusing on becoming profitable and preparing for a significant advance from 2016 to 2018. In fiscal 2017 ended March 31, 2018, the company generated profit, paid a commemorative interim dividend of  $\pm 10$  per share and plans to pay a year-end dividend of  $\pm 10$ . While cash outflow is expected for investing in areas of significant growth potential, cash inflow can also be expected from stable SMO, CRO, and Medical Support Businesses. I'rom Group is thus likely to carefully balance investment and financials, with consideration to need for external financing, and to expand its dividend policy.

Social contribution through its business activities

A for-profit company contributing to society

Contributing to enhancement of the quality of patients' lives and medical development by developing gene therapeutic products and other drugs in the Advanced Medicinal Treatment For raising sustainable corporate value, it is important to incorporate Environmental (E), Social contribution (S), and Governance (G) in the business structure. I'rom Group's major ESG activities are as follows:

#### **1.** Environment (E)

I'rom Group is working on raising employees' awareness on environmental issues so that they become considerate of the environment in every aspect of operations, starting from adjusting the temperature of the office, saving electricity to reduce its consumption, and thoroughly separating waste.

#### 2. Social (S)

While being a for-profit company, I'rom Group also contributes to society with its operations. Clinical trials are an indispensable process for new drug development and represent precious opportunities for patients suffering with no effective cure to be exposed to a new therapeutic method. A launch of a new drug may rescue patients who suffer from the disease. I'rom Group will make further efforts so that a new drug or therapeutic technology is delivered to patients as soon as possible.

In recent years, the medical industry has been highly anticipated to realize regenerative medicine and gene-based drugs, in addition to making developmental progress in treating diseases with unmet medical needs, such as cancer and intractable diseases. I'rom Group is contributing to enhancement of the quality of patients' lives and medical development by developing gene therapeutic products and other drugs in the Advanced Medicinal Treatment Business and by promptly and flexibly coping with changes in the medical field.

## Business and by promptly and flexibly coping with medical changes

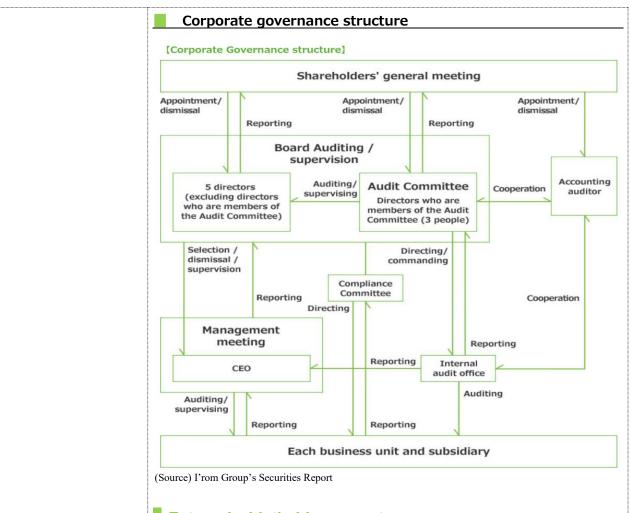
Moreover, thinking that all employees are management resources, I'rom Group is recognized for its offering of a suitable work environment for each of them. It has fostered a better working environment for women, who are now representing 84.1% of the workforce and 52.6% of executives in I'rom Group's SMO business companies. I'rom Group has empowered women by expanding positions suitable according to their life stage, hence supporting diversity and diverse ways of working across the entire group. As a result, many employees take maternity leave or childcare leave and about 90% of them return to workplace.

#### **3.** Governance (G)

Encourage a style of management that respects the position of its shareholders and other stakeholders in its disclosure of Group information through a range of opportunities and methods

I'rom Group encourages a style of management that respects the position of its shareholders and other stakeholders in its disclosure of group information through a range of opportunities and methods. I'rom Group believes that taking this approach helps to enhance the credibility of the Group and raise shareholder value. It is concentrating on building the systems to ensure this.

To give some specific examples of how I'rom Group is paying attention to ensuring transparency of management and working to enhance its corporate governance, I'rom Group is encouraging compliance with its Articles of Incorporation and with laws and regulations that strengthen monitoring and supervision by the auditors of the Board of Directors. It is ensuring timely and appropriate disclosure of information by prompting publishing it on our corporate website and through other channels.



#### External whistle-blower system

In compliance with the Whistle-Blower Protection Act and related regulations, I'rom Group has adopted the External Whistle-Blower System since August 2010, with the aim to early detect and correct actions contrary to corporate compliance (i.e., general regulations and laws, and I'rom Group's Code of Conduct) by employees and executives of I'rom Group and its related companies and to contribute to enhancement of its compliance system.

Prior to introducing this system, I'rom Group had an internal contact office for its employees and executives but has decided to establish an external contact office which can be used by its business partners so that I'rom Group can better ensure fair business and sound relationships with these partners.

Glossary	
Clinical trials	Trials conducted to be approved as drug by the Ministry of Health, Labour and Welfare
Regional medical care	Hospitals designated by a governor as appropriate facility to ensure local medical care, and with capacity to
support hospitals	support primary care doctors
Clinical trials	Trials to apply a drug with a certain level of efficacy and safety prove in pre-clinical trials to humans to further
	evaluate efficacy and safety
Early clinical trials	The first part of Phase I-III clinical trials
Advanced medical treatment	Advanced medical treatment specified by the Minister of Health, Labour, and Welfare. Its expenses are separated
	into a part covered by medical insurance and a part specified as advanced medical treatment.
GCP (Good Clinical	The Ministerial Ordinance on GCP for Drugs is established by the Ministry of Health, Labour, and Welfare to
Practices)	enable appropriate clinical trials in Japan based on the internationally agreed standard on conducting clinical trials. The GCP specifies details on roles and tasks of medical institutions and people engaged in trials. Compliance is required when conducting clinical trials.
SMO (Site Management	Organizations that support specialized tasks needed at medical institutions that conduct clinical trials
SMO (Site Management Organizations)	organizations that support specialized tasks needed at medical institutions that conduct chinical trials
CRO (Contract Research	Organizations that partially conduct and support tasks of clinical trials for a drug or a medical device for
Organizations)	pharmaceutical companies and other institutions
Clinic mall	Clinic space that offers many types of clinical departments to patients in one building where multiple medical institutions are domiciled
Intractable disease	A disease of unknown etiology with no effective treatment that presents a major financial and psychological
	burden to the patient and that is rare (Intractable Disease Health Care Act I)
Unmet medical needs	Medical needs for diseases that yet have no effective cure
Gene therapy	Therapeutic delivery of genes or gene-transduced cells into a patient's cells to treat disease
Regenerative medicine	A therapeutic technology to use regenerated cells with the aim to restore, repair, or establish normal tissues, organs or function
Inheritable genetic	A therapeutic method to take out anti-tumor T-cells from the patient's body and, after raising sensing technology
modification (IGM) type of	by IGM, to transplant the T-cells back to the patient's body
immune therapy	
High-function antibody	Antibody with high functionality, such as to combine medical agents or to combine agents into two target
XT 1 ' '1 1' '	molecules in one antibody
Nucleic acid medicine	Medicines that are synthesized and directly affect the body without expression of protein
Cell therapy	Therapy in which human cells, after being removed from the body, selected, activated, amplified, and
~	differentiated, are injected into a patient for treatment
Sendai virus vector	Sendai virus vector, developed by ID Pharma, a subsidiary of I'rom Group, is based on a different concept to that
	of other vectors developed in the past, and replicates its genome without entering the nucleus. Thus, no chance
***	that it alters the chromosomes.
Virus vector	Gene transduction method that make use of a mechanism that a virus infects cells
CRC (Clinical Research	Special staff who coordinate the overall clinical research to be appropriately conducted
Coordinators)	
Drug metabolism	Process to dissolve and eliminate drugs as the living body tries to clear foreign substances from the body
Medipolis Medical Research	An institute located in Kagoshima Prefecture that aims to promote research on diagnosis and treatment of chronic
Institute	diseases, including cancer and blood vessel disorder, and practical research on preventive medicine and
	psychosomatic care. At present, its main facility is Medipolis Proton Therapy and Research Center.
GMP (Good Manufacturing	Standards on production and quality management to ensure safety of medicines.
Practice)	
Drug screening	Part of the drug discovery process to evaluate and select a variety of compounds to choose effective compounds for a new drug
Therapeutic genes	Genes that are incorporate in virus vectors and achieve therapeutic effect on the patient
Pipeline	A pipeline is a drug candidate under development. The number of pipelines means the number of drugs being
ripenne	developed.
CPC (Cell Processing Center)	A facility specialized in cultivating and processing cells for clinical use
Mega pharmaceutical	Companies which have many drugs that can be used globally, and comprehensively develop new drugs that
companies	obtain a certain positioning in the global market
KKR (Federation of National	A federation of associations that was established to do works related to pension and welfare services for national
Public Service Personnel	public service personnel, jointly with affiliated mutual aid associations
Mutual Aid Associations)	
	Hospitals that are engaged in core medical treatments and function as a base to dispatch doctors
Core hospitals	In contrast to normal evaluation targeting 12 months for a new drug discovery from application to approval,
Core hospitals SAKIGAKE and	
SAKIGAKE and	drugs designated for the SAKIGAKE and Breakthrough Therapy are preferentially processed and target a six-
SAKIGAKE and Breakthrough Therapy	drugs designated for the SAKIGAKE and Breakthrough Therapy are preferentially processed and target a six- month evaluation period, using prior assessment conducted by the Pharmaceuticals and Medical Devices Agency
SAKIGAKE and Breakthrough Therapy Designation	month evaluation period, using prior assessment conducted by the Pharmaceuticals and Medical Devices Agency
SAKIGAKE and Breakthrough Therapy	month evaluation period, using prior assessment conducted by the Pharmaceuticals and Medical Devices Agency A theoretic or experimental research focused on formulating a hypothesis or a theory, or for obtaining new
SAKIGAKE and Breakthrough Therapy Designation Basic research	month evaluation period, using prior assessment conducted by the Pharmaceuticals and Medical Devices Agency A theoretic or experimental research focused on formulating a hypothesis or a theory, or for obtaining new knowledge on phenomenon or observable facts, without directly considering specific application or adoption
SAKIGAKE and Breakthrough Therapy Designation	month evaluation period, using prior assessment conducted by the Pharmaceuticals and Medical Devices Agency A theoretic or experimental research focused on formulating a hypothesis or a theory, or for obtaining new

Phase I	Sometimes referred to as "first-in-human studies." The first stage of clinical testing participated by a small group
Thase I	of healthy adults to determine safety of a drug candidate.
Phase II	Sometimes referred to as "proof-of-concept studies." The second stage of clinical testing participated by a
Thuse II	relatively small number of patients to determine safety and efficacy of a drug candidate.
Phase III	Sometimes referred to as "verifying studies." The third stage of clinical testing participated by a large group of patients to ultimately determine safety and efficacy of a drug candidate, based on the Phase II trial results.
Interim analysis	All analyses that are intended to compare trial treatments on efficacy or safety and are conducted before official completion of trials
Conditional early approval	Concerning drugs for serious diseases with no cure with efficacy, that are difficult to conduct confirmatory trials
system	due to lack of the number of patients, etc. or that require long-term trials, conditional manufacturing and marketing authorization are given after a certain level of safety and efficacy are confirmed, under the condition to subsequently further confirm efficacy and safety.
iPS (induced pluripotent	Stem cells that are created by inducing specific sets of genes to somatic cells and can be differentiated into all
stem) cells	types of tissues and cells.
Submission of a clinical trial plan	A clinical trial plan must be submitted to the Minister of Health, Labour and Welfare by sponsors (i.e., pharmaceutical companies) and doctors (who conduct clinical trials) to allow the Ministry to understand the situation from a hygiene perspective and to ensure safety of the trial.
In-Country Care-taker	Those who are in charge of all proceedings for clinical trials in Japan based on the request from someone who is not domiciled in Japan
Advanced medicine	Partial revision of Japan's National Insurance Act (No. 83, 2006) defines advanced medicine as "medical care that uses advanced medical technologies approved by the Minister of Health, Labour and Welfare and that needs to be evaluated from the perspective of efficiently providing appropriate medical care on whether to be covered by the national insurance." 101 types of advanced care as of January 1, 2018.
Yamanaka four factors	Genes identified by Professor Shinya Yamanaka of Kyoto University and others as transcription factors. They are Oct3/4, Sox2, Klf4, and c-Myc. By applying these four genes to cells which have lost pluripotent functionality, they can be differentiated into all types of cells in the human body.

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