Securities Code: 4506

Supplementary Financial Data (IFRS) for the Year Ended March 31, 2020

May 13, 2020

Sumitomo Dainippon Pharma Co., Ltd.

- This material contains forecasts, projections, targets, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such statements and involve both known and unknown risks and uncertainties. Accordingly, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

I. Consolidated Financial Highlights

1. Consolidated Statement of Profit or Loss (Core Basis)

(Billions of yen)

	FY2018	FY2019	Change % YoY	FY2020 (Forecast)	Change % YoY
Revenue	459.3	**482.8**	5.1	510.0	5.6
Cost of sales *1	113.1	**128.3**	13.5	145.0	13.0
Gross profit	346.2	**354.4**	2.4	365.0	3.0
SG&A expenses *1	186.1	**190.0**	2.1	229.0	20.5
R&D expenses *1	82.9	**92.6**	11.7	103.0	11.2
Other operating income/expenses (Core Basis)*2	0.2	**0.2**		-	
Core operating profit	77.3	**72.0**	(6.9)	33.0	(54.2)
Changes in fair value of contingent consideration (negative number indicates loss)	9.1	**48.5**		(24.0)	
Other non-recurring items *3 (negative number indicates loss)	(28.5)	**(37.2)**		15.0	
Operating profit	57.9	**83.2**	43.8	24.0	(71.2)
Net profit	48.6	**35.9**	(26.1)	(14.0)	-
Net profit attributable to owners of the parent	48.6	**40.8**	(16.2)	7.0	(82.8)
Basic earnings per share (yen)	122.39	**102.58**		17.62	
Net profit/ Equity attributable to owners of the parent (ROE)	10.2%	**7.9%**		1.3%	
Return on inveted capital (ROIC)	11.8%	**3.3%**		(0.6)%	
Payout ratio	22.9%	**27.3%**		158.9%	

*1 Exclude non-recurring items (impairment loss, changes in fair value of contingent consideration, etc.)
*2 "P/L on business transfer" and "share of P/L of associates accounted for using equity method"
*3 Non-recurring items ("other operating income and expenses" except for *2 items, impairment loss, etc.)

2. Consolidated Statement of Profit or Loss (Full Basis)

(Billions of yen)

	FY2018	FY2019	Change % YoY
Revenue	459.3	**482.7**	5.1
Cost of sales	113.6	**129.7**	14.2
Gross profit	345.7	**353.1**	2.1
SG&A expenses	180.4	**154.3**	(14.5)
R&D expenses	102.4	**115.1**	12.5
Other operating income/expenses	(5.0)	**(0.4)**	
Operating profit	57.9	**83.2**	43.8
Finance income/costs	7.2	**0.7**	
Profit before taxes	65.0	**83.9**	29.1
Net profit	48.6	**35.9**	(26.1)
Net profit attributable to owners of the parent	48.6	**40.8**	(16.2)

3. Consolidated Statement of Cash Flows

(Billions of yen)

	FY2018	FY2019
Net cash provided by operating activities	48.7	**46.1**
Net cash provided by (used in) investing activities	(35.0)	**(312.7)**
Net cash used in financing activities	(28.6)	**231.1**
Cash and cash equivalents at the end of period	137.3	**101.7**

4. Foreign Exchange Rates

	FY2018		FY2019		FY2020 assumption	Forex sensitivity FY2020 (Impact of yen depreciation by ¥1)	
	Period end rate	Average rate	**Period end rate**	**Average rate**	**Average rate**	Revenue	Core operating profit
Yen / USD	111.0	110.9	**108.8**	**108.7**	**108.0**	2.6	(0.6)
Yen / RMB	16.5	16.5	**15.3**	**15.6**	**15.5**	2.0	0.4

(Billions of yen)

5. Capital Expenditures/ Depreciation and Amortization

(Billions of yen)

	FY2018	**FY2019**	Change	FY2019 (Forecast)	Change
Capital expenditures	13.2	**12.0**	(1.2)	11.0	(1.0)
Property, plant and equipment	7.3	**10.5**	3.2	10.0	(0.5)
Intangible assets	6.6	**6.9**	0.2	12.9	6.0

Note: The amount of capital expenditures are for tangible fixed assets and software.

Major capital expenditure project in FY2020 (continued)

Reinforcement of production facilities, total budget ￥2.0billion, to be completed in FY2022

6. Valuations and Accounting Procedures Following the Company Acquisition through the Strategic Alliance with Roivant Sciences

($M)

	Before purchase price allocation	**After purchase price allocation**	Valuation differences	Accounting procedures
Intangible Assets (In-process R&D, etc.)	—	**265.9**	265.9	Capitalize (Amortize IPR&D after approval)
Deferred tax liabiliies (of the above)	—	**(24.7)**	(24.7)	
Other assets & liabilities (Net)	(4.1)	**(4.1)**	—	
Non-controlling interests	(2.5)	**(98.3)**	(95.8)	
Goodwill	—	**65.9**	65.9	
Total	(6.5)	**204.7**	211.3	

II. Consolidated Statement of Profit or Loss

1. Consolidated Statement of Profit or Loss (Core Basis)

(Billions of yen)

	FY2018	FY2019	Change	Change %
Revenue	459.3	**482.8**	23.5	5.1
Overseas revenue	293.3	**307.8**	14.5	4.9
% of Revenue	63.9%	**63.8%**		
Cost of sales	113.1	**128.3**	15.2	13.5
% of Revenue	24.6%	**26.6%**		
Gross profit	346.2	**354.4**	8.3	2.4
SG&A expenses	186.1	**190.0**	3.8	2.1
Labor costs	76.1	**80.7**	4.6	6.0
Advertising and promotion costs	23.2	**22.7**	(0.5)	(2.3)
Sales promotion costs	14.8	**15.1**	0.3	2.1
Amortization/Depreciation	7.9	**11.3**	3.4	43.4
Others	64.2	**60.2**	(4.0)	(6.2)
R&D expenses	82.9	**92.6**	9.7	11.7
% of Revenue	18.0%	**19.2%**		
Other operating income/expenses (Core Basis)	0.2	**0.2**	(0.0)	(13.1)
Core operating profit	77.3	**72.0**	(5.3)	(6.9)
Changes in fair value of contingent consideration *	9.1	**48.5**	39.3	
Other non-recurring items *	(28.5)	**(37.2)**	(8.7)	
Operating profit	57.9	**83.2**	25.4	43.8
Finance income	7.4	**3.6**	(3.8)	
Finance costs	0.2	**2.9**	2.7	
Profit before taxes	65.0	**83.9**	18.9	29.1
Income tax expenses	16.4	**48.0**	31.6	
Net profit	48.6	**35.9**	(12.7)	(26.1)
Net profit attibutable to owners of the parent	48.6	**40.8**	(7.9)	(16.2)

* Negative number indicates loss.

Revenue:

¥billion	Change	FX rate
Japan	10.4	
North America	9.8	(5.4)
China	3.9	(1.7)
Other Regions	0.5	
Other	(1.0)	

・Incremental cost by consolidating Sumitovant 6.5

・Incremental cost by consolidating Sumitovant 9.0

Changes in fair value of contingent consideration

	FY18	FY19
LONHALA®MAGNAIR®	1.9	*8.7
BBI	4.0	*26.2
Tolero	3.2	*13.6

* Decrease in fair value by revising business plans

・Impairment loss: FY18 (23.0) , FY19 (35.2)
Restructuring: FY18 (3.8)

・FY19: Reversal of deferred tax assets in U.S.

2. Adjustments to Core Operating Profit

(Billions of yen)

FY2019 Results	Full Basis	Core Basis	Adjustment	Major adjustment items
Revenue	482.7	**482.8**	0.0	
Cost of sales	129.7	**128.3**	(1.3)	Impairment loss (0.6)
Gross profit	353.1	**354.4**	1.4	
SG&A expenses	154.3	**190.0**	35.6	Changes in fair value of contingent consideration 48.5 Impairment loss (12.1)
R&D expenses	115.1	**92.6**	(22.5)	Impairment loss (22.5)
Other operating income	1.4	**0.1**	(1.3)	
Other operating expenses	1.8	**—**	(1.8)	
Operating profit	83.2	**72.0**	(11.3)	

III. Segment Information (Core Basis)

(Billions of yen)

FY2019 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	139.7	262.3	28.6	14.8	445.4	37.4	482.8
Cost of sales	65.0	24.0	5.4	5.0	99.5	28.9	128.3
Gross profit	74.7	238.3	23.2	9.8	346.0	8.4	354.4
SG&A expenses	51.8	120.8	8.8	3.4	184.8	5.2	190.0
Core segment profit	**22.9**	**117.5**	**14.4**	**6.4**	**161.2**	**3.2**	**164.4**
R&D expenses *1					91.7	0.9	92.6
Other operating income/expenses (Core basis)*2					0.1	0.0	0.2
Core operating profit					**69.7**	**2.3**	**72.0**

(Billions of yen)

FY2020 Forecasts	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	154.4	268.0	30.8	18.8	472.0	38.0	510.0
Cost of sales	80.0	23.0	5.8	6.9	115.7	29.3	145.0
Gross profit	74.4	245.0	25.0	11.9	356.3	8.7	365.0
SG&A expenses	55.0	154.3	10.4	3.6	223.3	5.7	229.0
Core segment profit	**19.4**	**90.7**	**14.6**	**8.3**	**133.0**	**3.0**	**136.0**
R&D expenses *1					102.0	1.0	103.0
Other operating income/expenses (Core basis)*2					-	-	-
Core operating profit					**31.0**	**2.0**	**33.0**

(Billions of yen)

(Ref.) FY2018 Results	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
Revenue (Sales to customers)	129.3	252.5	24.7	14.3	420.9	38.4	459.3
Cost of sales	52.4	21.7	3.7	5.6	83.4	29.7	113.1
Gross profit	77.0	230.8	21.0	8.7	337.5	8.6	346.2
SG&A expenses	51.9	116.3	8.7	3.6	180.6	5.6	186.1
Core segment profit	**25.1**	**114.5**	**12.3**	**5.0**	**157.0**	**3.1**	**160.0**
R&D expenses *1					81.8	1.1	82.9
Other operating income/expenses (Core basis)*2					0.2	0.0	0.2
Core operating profit					**75.3**	**2.0**	**77.3**

*1 R&D expenses for pharmaceuticals business are controlled globally and not allocated to each segment.

*2 P/L on business transfer and share of P/L of associates accounted for using equity method

IV. Revenues Information

1. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

Segment	FY2018	FY2019	Change	Change %	FY2020 (Forecast)
Japan	129.3	**139.7**	10.4	8.1	154.4
North America	252.5	**262.3**	9.8	3.9	268.0
China	24.7	**28.6**	3.9	15.6	30.8
Other Regions	14.3	**14.8**	0.5	3.5	18.8

2. Sales of Major Products (1)

(Invoice price basis, Billions of yen)

Brand name Therapeutic indication	FY2018	FY2019	Change	Change %	FY2020 (Forecast)
Japan					
Promoted products					
Trulicity® *1 Therapeutic agent for type 2 diabetes (Sep. 2015～)	23.1	**30.0**	6.9	29.6	36.6
Euqa®/EquMet® *2 Therapeutic agent for type 2 diabetes (Nov. 2019～)	–	**17.1**	17.1	–	40.5
TRERIEF® Therapeutic agent for Parkinson's disease	15.7	**16.2**	0.5	3.4	17.0
REPLAGAL® Therapeutic agent for Anderson-Fabry disease	12.5	**13.3**	0.8	6.3	13.3
METGLUCO® Therapeutic agent for type 2 diabetes	10.1	**9.6**	(0.4)	(4.3)	7.8
SUREPOST® Therapeutic agent for type 2 diabetes	6.1	**6.9**	0.8	13.2	3.0
AmBisome® Therapeutic agent for systemic fungal infection	4.0	**4.2**	0.1	3.6	4.0
LONASEN® Tape Atypical antipsychotic (Sep. 2019～)	–	**0.5**	0.5	–	5.3
LATUDA® Atypical antipsychotic (To be launched in June 2020)	–	**–**	–	–	2.2
Other products					
AMLODIN® Therapeutic agent for hypertension and angina pectoris	9.1	**7.6**	(1.5)	(16.2)	6.1
LONASEN® tablet/powder Atypical antipsychotic	12.2	**5.6**	(6.7)	(54.6)	2.3
AIMIX® Therapeutic agent for hypertension	8.2	**4.0**	(4.2)	(50.9)	2.9
PRORENAL® Vasodilator	4.0	**3.2**	(0.8)	(21.0)	2.2
GASMOTIN® Gastroprokinetic	3.8	**3.1**	(0.7)	(18.4)	2.3
Authorized Generics	5.5	**7.4**	1.9	34.0	9.4

*1 Trulicity® revenue is shown by NHI price.

*2 Excluding promotion fee revenue

2. Sales of Major Products (2)

(Billions of yen)

Brand name Therapeutic indication	FY2018	**FY2019**	Change	Change %	FY2020 (Forecast)
North Amrerica					
LATUDA® Atypical antipsychotic	184.5	**189.5**	5.0	2.7	194.2
BROVANA® Therapeutic agent for COPD	33.7	**34.5**	0.8	2.3	31.1
APTIOM® Antiepileptic	20.5	**23.4**	2.9	14.1	23.3
LONHALA® MAGNAIR® Therapeutic agent for COPD (Apr. 2018～)	1.4	**2.9**	1.5	105.0	3.8
XOPENEX® Therapeutic agent for asthma	4.6	**4.1**	(0.5)	(10.3)	4.1
Apomorphine hydrochloride (generic name) OFF episodes associated with Parkinson's disease (To be launched in Sep. 2020)	—	—	—	—	1.1
China					
MEROPEN®	21.2	**24.1**	2.8	13.2	25.3
Other Regions					
MEROPEN®	7.9	**8.1**	0.1	1.7	8.0

(Ref.) Products sales in North America (based on local currency) (Millions of dollar)

品目	FY2018	**FY2019**	Change	Change %	FY2020 (Forecast)
LATUDA®	1,663	**1,743**	80	4.8	1,798
BROVANA®	304	**317**	13	4.4	288
APTIOM®	185	**215**	30	16.5	216
LONHALA® MAGNAIR®	13	**27**	14	109.2	35
XOPENEX®	42	**38**	(4)	(8.5)	38
Apomorphine hydrochloride	—	—	—	—	10

V. Consolidated Statement of Financial Position

(Billions of yen)

	Mar.31 2019	Mar. 31 2020	Change
Assets	**834.7**	**1,252.9**	**418.2**
Non-current assets	**461.4**	**888.8**	**427.3**
Property, plant and equipmer	59.5	65.7	6.3
Goodwill	99.3	169.0	69.7
Intangible assets	171.4	421.8	250.4
Patent rights/Marketing rights	24.0	8.5	(15.5)
In-process R&D	141.4	406.3	264.8
Others	5.9	7.0	1.1
Other financial assets	74.7	200.9	126.3
Other non-current assets	5.8	4.2	(1.7)
Deferred tax assets	50.7	27.1	(23.6)
Current assets	**373.3**	**364.1**	**(9.2)**
Inventories	66.9	79.4	12.5
Trade and other receivables	118.8	134.5	15.7
Other financial assets	43.8	28.7	(15.0)
Other current assets	6.6	15.5	8.9
Cash and cash equivalents	137.3	101.7	(35.6)
Subtotal	373.3	359.8	(13.5)
Assets held for sale	—	4.3	4.3
Liabilities	**336.6**	**620.8**	**284.2**
Non-current liabilities	**138.4**	**124.3**	**(14.1)**
Bonds and borrowings	28.0	25.0	(3.0)
Other financial liabilities	80.4	41.3	(39.1)
Retirement benefit liabilities	23.6	23.9	0.3
Other non-current liabilities	6.4	7.2	0.8
Deferred tax liabilities	—	26.9	26.9
Current liabilities	**198.2**	**496.5**	**298.3**
Bonds and borrowings	3.0	273.0	270.0
Trade and other payables	49.2	62.3	13.0
Other financial liabilities	8.7	13.9	5.2
Income taxes payable	15.7	22.6	6.9
Provisions	92.2	84.6	(7.5)
Other current liabilities	29.4	40.1	10.7
Equity	**498.1**	**632.1**	**134.0**
Share capital	22.4	22.4	—
Capital surplus	15.9	14.7	(1.2)
Treasury shares	(0.7)	(0.7)	(0.0)
Retained earnings	431.8	457.3	25.5
Other components of equity	28.8	35.8	7.0
Equity attributable to owners of the parent	**498.1**	**529.5**	**31.3**
Non-controlling interests	—	102.6	102.6

Goodwill	19/3	20/3
Other than oncology	75.0	145.2
[Sumitovant]		[71.7]
Oncology	24.3	23.8

Patent right impairment in North America

IPR&D	19/3	20/3
Apomorphine	55.2	54.1
BBI products	30.0	*27.6
Tolero products	44.4	*26.1
Relgolix		175.1
Vibegron		109.0
Others	11.9	14.3

*Decrease mainly due to impairment loss

Acquisition of Roivant shares

Reversal of deferred tax assets in U.S.

Total bonds and borrowings
30.9 → 298.0
[New borrowing 270.0]

Contingent consideration liabilities	19/3	20/3	Total probable payment (Max)
LONHALA®MAGNAIR®	8.9	* -	$210M
BBI	44.5	*17.4	$1,390M
Tolero	27.9	*13.8	$580M
Total	81.4	31.2	

Included in "Other financial liabilities (Non current/Current)"

* Decrease by revising business plans

FX rate	19/3		20/3
USD	¥111.0	⇒	¥108.8
RMB	¥ 16.5	⇒	¥ 15.3

VI. Changes in Quarterly Results

(Billions of yen)

	FY2018				FY2019			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Revenue	115.9	110.2	120.7	112.4	117.5	113.1	126.4	**125.7**
Cost of sales	28.9	26.7	29.6	27.9	28.8	27.3	37.0	**35.3**
Gross profit	87.0	83.6	91.1	84.5	88.6	85.9	89.4	**90.5**
SG&A expenses	47.8	44.4	51.8	42.1	46.3	42.4	49.8	**51.4**
R&D expenses	20.9	20.5	20.6	20.9	20.0	21.0	20.2	**31.4**
Other operating income/expenses (Core Basis)	0.0	0.0	0.1	0.0	0.0	0.0	0.1	**0.0**
Core operating profit	18.4	18.7	18.7	21.4	22.3	22.5	19.5	**7.7**
Changes in fair value of contingent consideration (negative number indicates loss)	(2.5)	(4.4)	1.4	14.6	18.5	23.3	(0.9)	**7.7**
Other non-recurring items (negative number indicates loss)	(0.1)	(0.6)	(2.9)	(25.0)	(0.3)	(19.4)	(3.9)	**(13.6)**
Operating profit	15.8	13.8	17.2	11.1	40.4	26.4	14.6	**1.8**
Net profit	15.2	12.6	12.1	8.7	6.7	23.6	13.6	**(8.1)**
Net profit attributable to owners of the parent	15.2	12.6	12.1	8.7	6.7	23.6	13.6	**(3.2)**

VII. Major Consolidated Subsidiaries (As of March 31, 2020)

Domestic	Establish-ment	Ownership	Number of employees	Businesses
DSP Gokyo Food & Chemical Co., Ltd.	1947/10	100%	197	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.
DS Pharma Animal Health Co., Ltd.	2010/ 7	100%	89	Manufacturing, and sales of veterinary medicines, etc.
DS PharmaPromo Co., Ltd.	1998/ 6	100%	47	Manufacturing and sales of pharmaceuticals, etc.
Overseas	**Establish-ment**	**Ownership**	**Number of employees**	**Businesses**
Sunovion Pharmaceuticals Inc.	1984/ 1	100%	*1,616	Manufacturing and sales of pharmaceuticals
Sumitovant Biopharma, Inc.	2019/10	100%	43	Implement oversight of Sumitovant group companies and formulation of potential business strategies for consideration of its group companies
Myovant Sciences Ltd.	2016/ 2	52%	*213	R&D in the women's health, prostate cancer area
Urovant Sciences Ltd.	2016/ 1	75%	*69	R&D in the urology area
Enzyvant Therapeutics Ltd.	2016/ 1	100%	*23	R&D in the pediatric rare diseases area
Altavant Sciences Ltd.	2017/ 9	100%	*13	R&D in the respiratory rare diseases area
Spirovant Sciences Ltd.	2019/ 2	100%	*12	R&D in the cystic fibrosis gene therapy area
Boston Biomedical, Inc.	2006/11	100%	135	R&D in the oncology area
Tolero Pharmaceuticals, Inc.	2011/ 6	100%	56	R&D in the oncology area
Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.	2003/12	100%	733	Manufacturing and sales of pharmaceuticals

* Include employees of consolidated subsidiaries

(Reference) Number of employees and MRs

	As of Mar. 31, 2018		As of Mar. 31, 2019		As of Mar. 31, 2020	
consolidated / non-consolidated	6,268	3,402	6,140	3,067	**6,457**	**3,023**
MRs						
Japan Exclude managers/Total	1,130	1,260	1,120	1,240	**1,220**	**1,340**
U.S. Exclude managers/Total	830	930	720	820	**650**	**740**
China Exclude managers/Total	330	400	340	400	**330**	**400**

"MRs" include number of contracted MRs

VIII. Shareholder Positioning (As of March 31, 2020)

1. Total number of authorized shares: 1,500,000,000

2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 605,038)

3. Number of shareholders by category:

	Number of shareholders	Number of shares (Thousands)	Percentage of total (%)
Financial institutions	57	93,095	23.40
Securities companies	56	2,458	0.62
Other Japanese corporations	289	232,829	58.51
Corporations outside Japan, etc.	594	46,940	11.80
Individuals and others (Including treasury stock)	23,567	22,577	5.67
Total	24,563	397,900	100

Note: The numbers of shares are rounded down to the nearest thousand shares.

4. Major shareholders:

Shareholders	Number of shares held (Thousands)	Percentage of shareholding(%)
Sumitomo Chemical Co., Ltd.	205,634	51.76
The Master Trust Bank of Japan, Ltd. (Trust account)	29,364	7.39
Inabata & Co., Ltd.	18,555	4.67
Japan Trustee Services Bank, Ltd. (Trust account)	11,742	2.96
Nippon Life Insurance Company	7,581	1.91
SMBC Trust Bank Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
BNYM SA/NV FOR BNYM FOR BNYM GCM CLIENT ACCTS M ILM FE	4,907	1.24
Japan Trustee Services Bank, Ltd. (Trust account 7)	3,676	0.93
Aioi Nissay Dowa Insurance Co., Ltd.	3,104	0.78

Notes: 1: Percentage of shareholding is calculated excluding treasury stock (605,038 stocks).
2: The numbers of shares held are rounded down to the nearest thousand shares.

IX. Development Pipeline (As of May 13, 2020)

- This table shows clinical studies on indications for which the Sumitomo Dainippon Pharma Group aims to obtain approval in Japan, U.S. or China, and does not cover all clinical studies.
- For oncology area, the study for the most advanced development stage is listed if there are multiple studies with the same indication.
- The development stage is changed when Investigational New Drug Application/amended IND/ Clinical Trial Notification is filed/approved by the authority.

1. Psychiatry & Neurology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
APL-130277 (apomorphine hydrochloride)	OFF episodes associated with Parkinson's disease	U.S.	NDA submitted in March 2018 Received Complete Response Letter in January 2019 NDA resubmitted in November 2019
LONASEN® (blonanserin)	(New usage: pediatric) Schizophrenia	Japan	Phase 3
SEP-363856	Schizophrenia	U.S.	Phase 3
		Japan	Phase 1
	Parkinson's disease psychosis	U.S.	Phase 2
EPI-743 (vatiquinone)	Leigh syndrome	Japan	Phase 2/3
EPI-589	Parkinson's disease	U.S.	Phase 2
	Amyotrophic lateral sclerosis (ALS)	U.S.	Phase 2
		Japan	Phase 1
SEP-4199	Bipolar I depression	U.S., Japan	Phase 2 (Global clinical study)
DSP-6745	Parkinson's disease psychosis	U.S.	Phase 1
SEP-378608	Bipolar disorder	U.S.	Phase 1
DSP-3905	Neuropathic pain	U.S.	Phase 1
SEP-378614	Treatment resistant depression	U.S.	Phase 1
SEP-380135	Agitation in Alzheimer's disease	U.S.	Phase 1
DSP-1181	Obsessive compulsive disorder	Japan	Phase 1

2. Oncology

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
relugolix	Prostate cancer (Monotherapy)	U.S.	NDA submitted in April 2020
BBI608 (napabucasin)	Colorectal cancer (Combination therapy)	U.S., Japan	Phase 3 (Global clinical study)
	Hepatocellular carcinoma (Combination therapy)	U.S.	Phase 1/2
	Gastrointestinal cancer (Combination therapy)	U.S.	Phase 1/2
	Solid tumors (Combination therapy)	U.S.	Phase 1/2
DSP-2033 (alvocidib)	Acute myeloid leukemia (AML) (Combination therapy) (Refractory or relapsed patients)	U.S.	Phase 2
	Myelodysplastic syndromes (MDS) (Combination therapy)	U.S.	Phase 1/2
	Acute myeloid leukemia (AML) (Combination therapy) (Newly diagnosed patients)	U.S.	Phase 1
DSP-7888 (adegramotide/ nelatimotide)	Glioblastoma (Combination therapy)	U.S., Japan	Phase 2 (Global clinical study)
	Pediatric malignant gliomas (Monotherapy)	Japan	Phase 1/2
	Solid tumors (Combination therapy)	U.S.	Phase 1/2
TP-0903 (dubermatinib)	Solid tumors (Monotherapy / Combination therapy)	U.S., Japan	Phase 1
DSP-0509	Solid tumors (Monotherapy / Combination therapy)	U.S.	Phase 1/2
TP-0184	Anemia associated with myelodysplastic syndromes (Monotherapy)	U.S.	Phase 1/2
	Solid tumors (Monotherapy)	U.S.	Phase 1
DSP-0337	Solid tumors (Monotherapy)	U.S.	Phase 1
TP-1287	Solid tumors (Monotherapy)	U.S.	Phase 1
TP-3654	Solid tumors (Monotherapy)	U.S.	Phase 1
	Myelofibrosis (Monotherapy / Combination therapy)	U.S.	Phase 1
TP-1454	Solid tumors (Monotherapy / Combination therapy)	U.S.	Phase 1

3. Regenerative medicine / cell therapy

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
RVT-802	Pediatric congenital athymia	U.S.	BLA submitted in April 2019 Received Complete Response Letter in December 2019
Allo iPS cell-derived dopamine neural progenitor	Parkinson's disease	Japan	Phase 1/2 (Investigator-initiated clinical study)
HLCR011 (Allo iPS cell-derived retinal pigment epithelium)	Age-related macular degeneration (AMD)	Japan	Preparing for start of clinical study

4. Others

Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
vibegron	Overactive bladder (OAB)	U.S.	NDA submitted in December 2019
	Overactive bladder (OAB) in men with Benign prostatic hyperplasia (BPH)	U.S.	Phase 3
	IBS-associated pain	U.S.	Phase 2
relugolix	Uterine fibroids	Europe	MAA submitted in March 2020
		U.S.	Phase 3 (Global clinical study)
	Endometriosis	U.S.	Phase 3 (Global clinical study)
PXL008 (imeglimin)	Type 2 diabetes	Japan	Phase 3
rodatristat ethyl	Pulmonary arterial hypertension (PAH)	U.S.	Phase 2
MVT-602	Female infertility	Germany	Phase 2
URO-902	Overactive bladder (OAB)	U.S.	Phase 2

【Main revisions since the announcement of January 2020】

Changes	Brand name/ Product code (Generic name)	Proposed indication	Region	Development stage
Approval	SM-13496 (lurasidone hydrochloride)	Schizophrenia	Japan	Approved in March 2020
		Bipolar depression		
	RETHIO® (thiotepa)	(New indication) Conditioning Treatment Prior to Autologous Hematopoietic Stem Cell Transplantation (HSCT) for malignant lymphoma	Japan	Approved in March 2020 * Development for the use of unapproved or off-labeled drugs
Submitted	relugolix	Uterine fibroids	Europe	MAA sbmitted in March 2020
		Prostate cancer (Monotherapy)	U.S.	NDA submitted in April 2020
Newly added because of studies started	TP-0184	Anemia associated with myelodysplastic syndromes (Monotherapy)	U.S.	Phase 1/2
	TP-1454	Solid tumors (Monotherapy)	U.S.	Phase 1
Deleted from the table due to the study completed	DSP-2033 (alvocidib)	Acute myeloid leukemia (AML) (Combination therapy) (Newly diagnosed and refractory or relapsed patients)	Japan	Phase 1
	DSP-7888 (adegramotide/ nelatimotide)	Myelodysplastic syndromes (MDS) (Monotherapy)	Japan	Phase 1/2
	TP-0903 (dubermatinib)	Chronic lymphocytic leukemia (CLL) (Monotherapy / Combination therapy)	U.S.	Phase 1/2
Deleted from the table due to discontinuation	SEP-225289 (dasotraline)	Binge eating disorder (BED)	U.S.	NDA submitted in May 2019
		Attention-deficit hyperactivity disorder (ADHD)	U.S.	NDA submitted in August 2017 Received Complete Response Letter in August 2018
			Japan	Phase 1

X. Profiles of Major Products under Development (As of May 13, 2020)

1. Psychiatry & Neurology

apomorphine hydrochloride (APL-130277) Developed in-house (Sunovion Pharmaceuticals Inc., from former Cynapsus Therapeutics), Formulation: sublingual film

- APL-130277 is a sublingual film formulation of apomorphine, a dopamine agonist, which is the molecule approved for acute intermittent treatment of OFF episodes associated with Parkinson's disease. It is designed to rapidly, safely and reliably convert a Parkinson's disease patient from the OFF to the ON state while avoiding many of the issues associated with subcutaneous delivery of apomorphine.
- Development stage: NDA submitted in the U.S. in March 2018
  NDA resubmitted in the U.S. in November 2019

SEP-363856 Developed in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- SEP-363856 is an antipsychotic agent with a novel mechanism of action a TAAR1 (trace amine-associated receptor 1) agonist with serotonin 5-HT_{1A} agonist activity and doesn't bind to dopamine D_2 or serotonin 5-HT_{2A} receptors. Sunovion discovered SEP-363856 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. Phase 2 results in patients with schizophrenia support the efficacy of SEP-363856 in treating both positive and negative symptoms of schizophrenia, while demonstrating a side effect of profile with notable similarities to placebo; extrapyramidal symptoms, weight gain, lipid and glucose derangements, cardiovascular abnormalities or prolactin elevation.
- Development stage:
  Schizophrenia: Phase 3 in the U.S.
  Parkinson's disease psychosis: Phase 2 in the U.S.
  Schizophrenia: Phase 1 in Japan

vatiquinone (EPI-743) In-licensed from PTC Therapeutics, Inc. (Acquired from BioElectron Technology Corporation), Formulation: oral

- EPI-743 is expected to show efficacy by removing the oxidative stress that is generated excessively by decreased mitochondrial function. It is expected to be the world's first treatment for mitochondrial diseases, beginning with Leigh syndrome, for which there is no effective therapy.
- Development stage:
  A Phase 2 / 3 study for Leigh syndrome in Japan completed, development strategy under consideration

EPI-589 In-licensed from PTC Therapeutics, Inc. (Acquired from BioElectron Technology Corporation), Formulation: oral

- EPI-589 is expected to show efficacy by removing the oxidative stress that is generated excessively by decreased mitochondrial function. It is expected to be developed for neurodegenerative indications arising through redox stress.
  Development stage:
  Parkinson's disease: Phase 2 in the U.S.
  Amyotrophic lateral sclerosis (ALS): Phase 2 in the U.S.
  Amyotrophic lateral sclerosis (ALS): Phase 1 in Japan

SEP-4199 Developed in-house (Sunovion Pharmaceuticals Inc.), Formulation: oral

- SEP-4199 is investigated for the treatment of major depressive episodes associated with bipolar I disorder. The mechanism of action is not disclosed at this time.
- Development stage:
  Bipolar I depression: Phase 2 in the U.S. and Japan

DSP-6745 Developed in-house, Formulation: oral

- DSP-6745 is a serotonin 5-HT_{2A} and serotonin 5-HT_{2C} receptors dual antagonist, which is expected to be effective for Parkinson's disease psychosis and one or more Parkinson's disease non-motor symptoms (depression, anxiety, or cognitive impairment). In addition, DSP-6745 has negligible affinity for dopamine D_2 receptors.
- Development stage: Parkinson's disease psychosis: Phase 1 in the U.S.

SEP-378608 Developed in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- SEP-378608 is a novel CNS-active molecule. Sunovion discovered SEP-378608 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. Pre-clinical studies suggest that it may modulate neuronal activity in key areas of the brain associated with the regulation of mood.
- Development stage: Bipolar disorder: Phase 1 in the U.S.

DSP-3905 Developed in-house, Formulation: oral

- DSP-3905 is an agent that selectively inhibits voltage-gated sodium channels Nav1.7. Based on its inhibitory mode of action, the agent is expected to show a potent analgesic effect on the pain occurring when neurons get excessively excited. In addition, DSP-3905 has a high selectivity for Nav1.7 expressed in peripheral neuron and may not produce central nervous system or cardiovascular system side effects, which are present with the current drugs for neuropathic pain.
- Development stage: Neuropathic pain: Phase 1 in the U.S.

SEP-378614 Developed in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- SEP-378614 is a novel CNS-active molecule. Sunovion discovered SEP-378614 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. Pre-clinical studies suggest that it may have rapid onset and long lasting antidepressant-like activity and enhance neuroplasticity.
- Development stage: Treatment resistant depression: Phase 1 in the U.S.

SEP-380135 Developed in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- SEP-380135 is a novel CNS-active molecule. Sunovion discovered SEP-380135 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. Pre-clinical studies showed a broad range of in vivo activities suggesting efficacy against a number of behavioral and psychological symptoms in dementia, including agitation/aggression, psychomotor hyperactivity, depression and deficits in social interaction.
- Development stage: Agitation in Alzheimer's disease: Phase 1 in the U.S.

DSP-1181 Developed in-house, Formulation: oral

- DSP-1181 is a novel compound created by Sumitomo Dainippon Pharma using Exscientia's AI technologies. In contrast to conventional serotonin 5-HT_{1A} receptor partial agonists (non-benzodiazepine anxiolytics), DSP-1181 has a potent full agonistic activity for serotonin 5-HT_{1A} receptors and is expected to have a long half-life, therefore it is suggested that DSP-1181 has strong efficacy over a long period of time. In Obsessive compulsive disorder (OCD) model mice manipulated OCD-related neural circuit, DSP-1181 is expected to have an earlier onset of efficacy than a standard medication, a selective serotonin reuptake inhibitor (SSRI).
- Development stage: Obsessive compulsive disorder: Phase 1 in Japan.

2. Oncology

napabucasin (BBI608) Developed in-house (Boston Biomedical, Inc.), Formulation: oral

- BBI608 is an orally administered small molecule agent with a novel mechanism of action which is bioactivated by the enzyme NQO1 in cancer cells, which generates reactive oxygen species (ROS) to inhibit cancer stemness and tumor progression-related pathways including STAT3, which is expected to result in cancer cell death.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 3	Colorectal cancer (combination therapy)	U.S., Japan	FOLFIRI[*3], FOLFIRI[*3] + bevacizumab	CanStem303C
Phase 1 / 2	Solid tumors[*1] (combination therapy)	U.S.	paclitaxel	201
	Hepatocellular carcinoma[*2] (combination therapy)	U.S.	sorafenib	HCC-103
	Solid tumors (combination therapy)	U.S.	ipilimumab, pembrolizumab, nivolumab	201CIT
	Gastrointestinal cancer (combination therapy)	U.S., Canada	FOLFOX[*3], FOLFOX[*3] + bevacizumab, CAPOX[*3], FOLFIRI[*3], FOLFIRI[*3] + bevacizumab, regorafenib, irinotecan	246
Phase 1	Pancreatic cancer (combination therapy)	U.S.	gemcitabine + nab-paclitaxel, FOLFIRINOX[*3], FOLFIRI[*3], irinotecan liposome injection + fluorouracil + leucovorin	118

*1 Phase 2 stage: Ovarian cancer, Breast cancer, Melanoma, etc.
*2 Phase 2 stage
*3 FOLFOX: Combination therapy with fluorouracil, leucovorin, oxaliplatin
CAPOX: Combination therapy with capecitabine, oxaliplatin
FOLFIRI: Combination therapy with fluorouracil, leucovorin, irinotecan
FOLFIRINOX: Combination therapy with fluorouracil, leucovorin, irinotecan, oxaliplatin

alvocidib (DSP-2033) In-licensed from Sanofi S.A., Formulation: injection

- Alvocidib is a small molecule inhibitor of cyclin-dependent kinase 9 (CDK9), a member of cyclin-dependent kinase family, which activates transcription of cancer-related genes. The subsequent down-regulation of MCL-1, an anti-apoptotic gene, may be responsible for the potential clinical anti-cancer activity observed with alvocidib.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 2	Acute myeloid leukemia (combination therapy) (refractory or relapsed patients)	U.S.	cytarabine, mitoxantrone	TPI-ALV-201 (Zella 201)

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 2	Acute myeloid leukemia (monotherapy/combination therapy) (refractory or relapsed patients following treatment with venetoclax combination therapy)	U.S.	cytarabine	TPI-ALV-202
Phase 1/2	Myelodysplastic syndromes (combination therapy)	U.S.	decitabine, azacitidine	TPI-ALV-102 (Zella 102)
Phase 1	Acute myeloid leukemia (combination therapy) (newly diagnosed patients)	U.S.	cytarabine, daunorubicin	TPI-ALV-101 (Zella 101)
	Acute myeloid leukemia (combination therapy) (refractory or relapsed patients)	U.S.	venetoclax	M16-186*

***** Co-development with AbbVie

adegramotide/nelatimotide (DSP-7888) Developed in-house, Formulation: injection

- DSP-7888 is a therapeutic cancer peptide vaccine derived from Wilms' tumor gene 1 (WT1) protein. DSP-7888 is a vaccine containing peptides that induces WT1-specific cytotoxic T lymphocytes (CTLs) and helper T cells. DSP-7888 is expected to become a treatment option for patients with various types of hematologic malignancies and solid tumors that express WT1, by inducing WT1-specific CTLs that attack WT1-expressing cancer cells. By adding a helper T cell-inducing peptide, improved efficacy over that observed with a CTL-inducing peptide alone may be achieved. DSP-7888 is expected to be an option for a wide range of patients.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 2	Glioblastoma (combination therapy)	U.S., Japan	Bevacizumab	BBI-DSP7888-201G
Phase 1/2	Pediatric malignant gliomas (monotherapy) *	Japan	-	DB601001
	Solid tumors (combination therapy)	U.S.	nivolumab, pembrolizumab	BBI-DSP7888-102CI

* Phase 2 stage

dubermatinib (TP-0903) In-licensed from University of Utah, Formulation: oral

- TP-0903 is an inhibitor of multikinase including AXL receptor tyrosine kinase inhibitor, which is known to be involved in acquiring resistance to conventional agents and developing metastatic capacity in cancer cells. TP-0903 may have anti-cancer activities on various cancer types through blocking transition from epithelial to mesenchymal phenotype by inhibiting AXL. TP-0903 has been shown to inhibit AXL signaling and reverse the mesenchymal to epithelial phenotype in pre-clinical studies.
- Development stage:
  Solid tumors (monotherapy / combination therapy): Phase 1 in the U.S. and Japan

DSP-0509 Developed in-house, Formulation: injection

- DSP-0509 is a novel Toll-like receptor (TLR) 7 agonist. DSP-0509 may promote the cytokine induction and cytotoxic T lymphocyte (CTL) activation mediated by agonistic effect of TLR 7 expressing in plasmacytoid dendritic cell. Furthermore, DSP-0509 is expected to sustain the immune-mediated anti-cancer activity by induction of immune system memory T cells.
- Development stage: Solid tumors (monotherapy / combination therapy): Phase 1/2 in the U.S.

TP-0184 Developed in-house (Tolero Pharmaceuticals, Inc.), Formulation: oral

- TP-0184 has an inhibitory effect against kinase such as ALK2 and ALK5, part of the transforming growth factor beta (TGFβ) receptor superfamily. In myelodysplastic syndromes, the ALK5 pathway is activated and caused abnormal erythroid differentiation. TP-0184 is expected to show anti-cancer activities through the kinase inhibitory effect.
- Development stage:
  Anemia associated with myelodysplastic syndromes (monotherapy): Phase 1/2 in the U.S.
  Solid tumors (monotherapy): Phase 1 in the U.S.

DSP-0337 Developed in-house, Formulation: oral

- DSP-0337 is a small molecule oral prodrug of napabucasin. DSP-0337 is expected to be stable and dispersed in the stomach, and converted to napabucasin in the intestine, which may be absorbed and exert its pharmacologic activities.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

TP-1287 Developed in-house (Tolero Pharmaceuticals, Inc.), Formulation: oral

- TP-1287 is a small molecule oral agent that inhibits cyclin-dependent kinase 9 (CDK9). TP-1287 has shown favorable oral bioavailability in preclinical studies. It is enzymatically cleaved, yielding alvocidib, a potent inhibitor of CDK9. The oral administration of TP-1287 may allow for administration for a prolonged period, which may lead to a continuous inhibition of CDK9.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

TP-3654 Developed in-house (Tolero Pharmaceuticals, Inc.), Formulation: oral

- TP-3654 inhibits the inflammatory signaling pathways through inhibition of PIM (proviral integration site for Moloney murine leukemia virus) kinases. PIM kinases are frequently overexpressed in various hematologic malignancies and solid tumors, allowing cancer cells to evade apoptosis and promoting tumor growth.
- Development stage:
  Solid tumors (monotherapy): Phase 1 in the U.S.
  Myelofibrosis (monotherapy / combination therapy): Phase 1 in the U.S.

TP-1454 Developed in-house (Tolero Pharmaceuticals, Inc.), Formulation: oral

- TP-1454 inhibits tumor growth through activation of PKM2 (pyruvate kinase M2) which lead to the inhibition of tumor cell proliferation and enhances antitumor immune response in tumor microenvironment. TP-1454 induce the activity of PKM2 through tetramerization of the enzyme which mainly exists in enzymatically less active dimer state in cancer cells. Tetramerization of PKM2 lead to the reduction of aerobic glycolysis in cancer cells and revert the immunosuppressive microenvironment. TP-1454 is expected to show synergistic effect with immune checkpoint inhibitor.
- Development stage:
  Solid tumors (monotherapy / combination therapy): Phase 1 in the U.S.

3. Regenerative medicine / cell therapy

RVT-802 In-licensed from Duke University

- RVT-802, a one-time regenerative therapy, is cultured human thymus tissue engineered to generate a functioning immune response when implanted in pediatric patients with congenital athymia. The key source material for RVT-802 is human thymus tissue that has been removed during pediatric cardiac surgery for unrelated conditions. Patients receive RVT-802 in the quadricep muscle during a single surgical procedure. The patient's own bone marrow stem cells migrate to RVT-802, where they develop into mature T-cells that can fight infection. For patients who respond to RVT-802, a diverse T-cell population is established and thymic function sufficient to protect from infection usually develops between 6 and 12 months post treatment.
- Development stage: Pediatric congenital athymia: BLA submitted in the U.S. in April 2019,
  Complete Response Letter received in December 2019

Allo iPS cell-derived products

- In cooperation with the partners in the industry-academia collaboration, we are promoting toward the commercialization of regenerative medicine / cell therapy using allo iPS cell (healthy patients) for AMD (age-related macular degeneration), Parkinson's disease, retinitis pigmentosa, and spinal cord injury.
- Development stage:

Development code	Partnering	Proposed indication	Area	Development stage
-	Kyoto University CiRA	Parkinson's disease	Japan	Phase 1/2 (Investigator-initiated clinical study)
HLCR011	RIKEN, Healios	Age-related macular degeneration (AMD)	Japan	Preparing for start of clinical study

4. Others

vibegron In-licensed from Merck Sharp & Dohme Corp., Formulation: oral

- Vibegron is an oral, once-daily, small molecule β3 adrenergic receptor agonist. Vibegron selectively acts on the β3 adrenergic receptor in the bladder, relaxes the bladder, enhances urinary storage, and improves symptoms of urgency, urinary frequency, and urge urinary incontinence in overactive bladder.
- Development stage:
  Overactive bladder: NDA submitted in the U.S. in December 2019
  Overactive bladder in men with BPH: Phase 3 in the U.S.
  IBS-associated pain: Phase 2 in the U.S.

relugolix In-licensed from Takeda Pharmaceutical Company Ltd, Formulation: oral

- Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces testicular testosterone production, the hormone primarily responsible for stimulating prostate cancer, and ovarian estradiol and progesterone production, hormones known to stimulate the growth of uterine fibroids and endometriosis. Myovant is developing a relugolix monotherapy tablet (120 mg) for men with advanced prostate cancer. Myovant is developing a distinct product, relugolix combination tablet (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) for uterine fibroids and endometriosis.
- Development stage:
  Uterine fibroids: MAA sbmitted in Europe in March 2020, Phase 3 in the U.S.
  Prostate cancer: NDA submitted in the U.S. in April 2020
  Endometriosis: Phase 3 in the U.S.

imeglimin (PXL008) In-licensed from Poxel SA, Formulation: oral

- Imeglimin is a new chemical substance classified as a tetrahydrotriazine compound, and the first clinical candidate in a chemical class. Imeglimin has a unique mechanism of action that targets mitochondrial bioenergetics. Imeglimin acts on all three key organs which play an important role in the treatment of type 2 diabetes: the pancreas, muscles, and the liver, and it has demonstrated glucose lowering benefits by increasing insulin secretion in response to glucose, improving insulin sensitivity and suppressing gluconeogenesis.
- Development stage: Type 2 diabetes: Phase 3 in Japan (Co-development with Poxel)

rodatristat ethyl In-licensed from Karos Pharmaceuticals, Inc., Formulation: oral

- Rodatristat ethyl is a prodrug of tryptophan hydroxylase (TPH) inhibitor designed to reduce peripheral production of serotonin without entering the brain. It is believed that rodatristat ethyl may halt or reverse the pathology of diseases that are driven by excessive serotonin production, such as PAH, idiopathic pulmonary fibrosis (IPF) and sarcoidosis.
- Development stage: Pulmonary arterial hypertension (PAH): Phase 2 in the U.S.

MVT-602 In-licensed from Takeda Pharmaceutical Company Ltd, Formulation: oral

- MVT-602 is an oligopeptide kisspeptin-1 receptor agonist. Activation of kisspeptin in upstream hypothalamic neurons is hypothesized to lead to the transmission of a signal that stimulates downstream neurons to increase the secretion of GnRH. Continued stimulation of kisspeptin is thought to result in the desensitization of receptor transduction, which is anticipated to result in a complete cessation of the signaling pathway. Myovant is developing MVT-602 as part of the hormonal preparation for women with infertility undergoing in vitro fertilization. MVT-602 is believed to stimulate GnRH which in turn increases secretion of luteinizing hormone that acts as a trigger for egg maturation prior to oocyte collection.
- Development stage: Female infertility: Phase 2 in Germany

URO-902 In-licensed from Ion Channel Innovations, Formulation: injection

- URO-902 is a novel gene therapy for patients with overactive bladder symptoms who have failed oral pharmacologic therapy. URO-902 is a plasmid vector containing a human cDNA encoding the pore-forming component of the Maxi-K ion channel. Expression of the Maxi-K protein in muscle cells is hypothesized to increase potassium ion flow across the cell membrane, reducing excitability of smooth muscle cells. This mechanism could potentially normalize the heightened detrusor smooth muscle tone in overactive bladder, thereby reducing the symptoms of overactive bladder.
- Development stage: Overactive bladder: Phase 2 in the U.S.