



Sumitomo Dainippon  
Pharma

First Quarter Financial Results for FY2014  
(April 1 to June 30, 2014)

July 30, 2014

Sumitomo Dainippon Pharma Co., Ltd.

# FY2014 1Q Financial Results

Billions of yen

	FY2013 1Q	FY2014 1Q	Change			FY2014 2Q		FY2014	
			Value		Percentage (%)	Previous forecasts *	Progress (%)	Previous forecasts *	Progress (%)
				Exchange Impact					
Net sales	89.6	<b>89.7</b>	0.1	1.2	0.1	178.0	50.4	352.0	25.5
Cost of sales	25.3	<b>24.1</b>	(1.2)	0.1	(4.7)	51.5	46.8	102.5	23.5
Gross profit	64.4	<b>65.7</b>	1.3	1.1	2.0	126.5	51.9	249.5	26.3
SG&A expenses	55.3	<b>57.0</b>	1.6	1.1	2.9	114.5	49.8	229.5	24.8
SG&A expenses less R&D costs	40.6	<b>41.8</b>	1.1	0.8	2.7	82.0	50.9	159.5	26.2
R&D Costs	14.7	<b>15.2</b>	0.5	0.3	3.6	32.5	46.8	70.0	21.7
Operating income	9.0	<b>8.7</b>	(0.3)	0.0	(3.7)	12.0	72.5	20.0	43.5
Ordinary income	9.5	<b>9.6</b>	0.1		0.6	11.5	83.1	19.0	50.3
Net income	4.8	<b>5.8</b>	0.9		19.7	6.3	91.4	12.0	48.0
E B I T D A	16.8	<b>14.9</b>				21.0		38.0	

\* Some part of forecasts have been revised.

Exchange Rate:

FY2013 1Q : 1US\$ = ¥ 98.8, 1RMB = ¥16.1

FY2014 1Q : 1US\$ = ¥102.2, 1RMB = ¥16.4

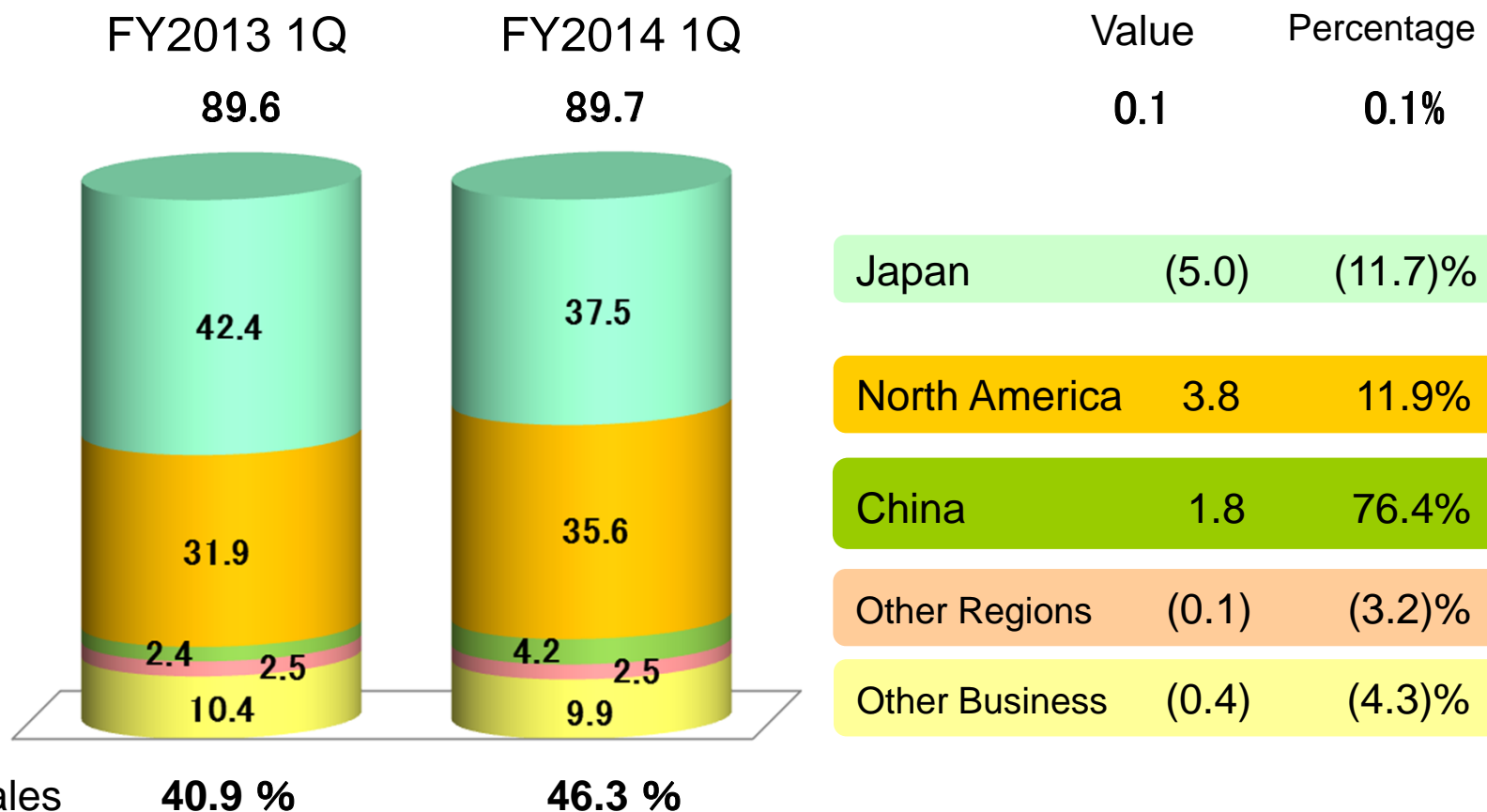
FY2014 : 1US\$ = ¥100.0, 1RMB = ¥16.0 1  
(previous forecast)



# 1Q Net Sales by Segment

Billions of yen

Change



**【 Japan 】** Effect from NHI price revision and decrease in long-term listed products

**【 North America 】** Growth of LATUDA®, drop in LUNESTA®(loss of exclusivity in April)

**【 China 】** Strong sales of MEROPEN®

Exchange Rate:

FY2013 1Q : 1US\$ = ¥ 98.8, 1RMB = ¥16.1

FY2014 1Q : 1US\$ = ¥102.2, 1RMB = ¥16.4

# 1Q Sales in Japan

Billions of yen

	FY2013 1Q	FY2014 1Q	Change		FY2014 2Q	
			Value	Percentage (%)	Previous forecasts *	Progress (%)
AIMIX®	0.8	2.6	1.7	212.1	5.5	46.8
AVAPRO®	3.0	2.8	(0.2)	(8.1)	5.5	50.4
LONASEN®	3.0	2.3	(0.6)	(21.7)	6.7	34.8
TRERIEF®	2.1	2.4	0.4	17.1	5.5	43.8
Strategic Products Total	8.9	10.1	1.2	13.6	23.2	43.5
METGLUCO®	3.5	3.6	0.1	3.0	7.9	46.2
SUREPOST®	0.3	0.5	0.1	41.6	1.5	31.1
New Products Total	3.9	4.1	0.2	6.3	9.4	43.8
AmBisome®	1.1	0.9	(0.2)	(20.4)	2.6	34.9
MIRIPLA®	0.3	0.2	(0.1)	(30.4)	0.5	41.7
REPLAGAL®	2.6	2.4	(0.2)	(6.3)	5.4	44.4
Specialty Products Total	4.0	3.5	(0.5)	(12.1)	8.5	41.4
AMLODIN®	7.2	5.1	(2.1)	(28.9)	11.5	44.4
GASMOTIN®	4.0	2.7	(1.3)	(32.6)	5.9	46.0
PRORENAL®	3.5	2.7	(0.9)	(24.3)	5.9	45.3
MEROPEN®	2.5	2.0	(0.4)	(17.5)	4.2	48.3
Others	8.5	7.3	(1.3)	(14.8)	16.0	45.3
<b>Japan Total</b>	42.4	37.5	(5.0)	(11.7)	84.6	44.3

Note: Sales figures are before reduction of rebates

\* Forecasts of some products have been revised.

# 1Q Sales in North America & China

	FY2013 1Q	FY2014 1Q	Change	FY2013 1Q	FY2014 1Q	Change		FY2014 2Q		
						Value	Exchange Rate Impact	Previous forecasts *		Yen-based Progress
<b>North America</b>	(Million \$)			(Billion yen)				(Million \$)	(Billion yen)	(%)
LATUDA®	68	<b>180</b>	112	6.8	<b>18.4</b>	11.6	0.6	295	29.5	62.3
LUNESTA®	136	<b>46</b>	(90)	13.4	<b>4.7</b>	(8.7)	0.2	61	6.1	77.9
XOPENEX®	36	<b>24</b>	(12)	3.5	<b>2.4</b>	(1.1)	0.1	59	5.9	41.2
BROVANA®	41	<b>46</b>	6	4.0	<b>4.7</b>	0.7	0.2	97	9.7	48.9
Ciclesonide	23	<b>16</b>	(7)	2.2	<b>1.6</b>	(0.6)	0.1	47	4.7	34.0
APTIOM®	—	<b>8</b>	8	—	<b>0.9</b>	0.9	—	12	1.2	70.9
Industrial property revenues	10	<b>12</b>	3	0.9	<b>1.3</b>	0.3	0.0	17	1.7	74.7
Others	9	<b>16</b>	6	0.9	<b>1.6</b>	0.7	0.0	21	2.1	76.8
<b>Total</b>	<b>323</b>	<b>349</b>	<b>26</b>	<b>31.9</b>	<b>35.6</b>	<b>3.8</b>	<b>1.2</b>	<b>609</b>	<b>60.9</b>	<b>58.5</b>
<b>China</b>	(Million RMB)			(Billion yen)				(Million RMB)	(Billion yen)	(%)
MEROPEN®	114	<b>213</b>	99	1.8	<b>3.5</b>	1.7	0.1	350	5.6	62.4
Others	35	<b>44</b>	10	0.6	<b>0.7</b>	0.2	0.0	81	1.3	55.8
<b>Total</b>	<b>149</b>	<b>257</b>	<b>109</b>	<b>2.4</b>	<b>4.2</b>	<b>1.8</b>	<b>0.1</b>	<b>431</b>	<b>6.9</b>	<b>61.2</b>

Exchange Rate:

FY2013 1Q : 1US\$ = ¥ 98.8, 1RMB = ¥16.1

FY2014 1Q : 1US\$ = ¥102.2, 1RMB = ¥16.4

FY2014 : 1US\$ = ¥100.0, 1RMB = ¥16.0

(previous forecast)

\* Forecasts of some products have been revised.



# 1Q Segment Breakdown for North America

< Excluding amortization of patent rights and goodwill, etc. >

	FY2013 1Q	<b>FY2014 1Q</b>	Change	FY2013 1Q	<b>FY2014 1Q</b>	Change	Exchange Rate Impact
	(Million \$)			(Billion yen)			
Net sales	323	<b>349</b>	26	31.9	<b>35.6</b>	3.8	1.2
Cost of sales	39	<b>30</b>	(9)	3.9	<b>3.0</b>	(0.8)	0.1
Gross profit	283	<b>319</b>	36	28.0	<b>32.6</b>	4.6	1.1
SG&A expenses	174	<b>206</b>	32	17.2	<b>21.1</b>	3.9	0.7
Income (loss) of Segment	110	<b>113</b>	3	10.8	<b>11.5</b>	0.7	0.4

< Amortization of patent rights and goodwill, etc. >

	FY2013 1Q	<b>FY2014 1Q</b>	Change	FY2013 1Q	<b>FY2014 1Q</b>	Change	Exchange Rate Impact
	(Million \$)			(Billion yen)			
SG&A expenses	53	<b>26</b>	(27)	5.2	<b>2.6</b>	(2.6)	0.1
Income (loss) of Segment	(53)	<b>(26)</b>	27	(5.2)	<b>(2.6)</b>	2.6	(0.1)

Exchange Rate:

FY2013 1Q : 1US\$ = ¥ 98.8

FY2014 1Q : 1US\$ = ¥102.2

# 1Q Segment Information

Billions of yen

		Pharmaceuticals Business					Subtotal	Other Business	Total	
		Japan	North America※1	Amortization※2	China	Other Regions				
FY2014 1Q Results	Net sales (Sales to customers)	37.5	35.6	—	4.2	2.5	79.8	9.9	89.7	
	Cost of sales	11.2	3.0	—	0.6	1.4	16.2	7.8	24.1	
	Gross profit	26.3	32.6	—	3.6	1.0	63.6	2.1	65.7	
	SG&A expenses less R&D costs	14.4	21.1	2.6	1.6	0.5	40.2	1.5	41.8	
	<b>Income (loss) of Segment</b>	11.9	11.5	(2.6)	2.0	0.5	23.3	0.6	23.9	
	R&D costs							15.0	0.2	15.2
	Operating income							8.3	0.4	8.7
FY2013 1Q Results	Net sales (Sales to customers)	42.4	31.9	—	2.4	2.5	79.2	10.4	89.6	
	Cost of sales	11.4	3.9	—	0.6	1.3	17.2	8.0	25.3	
	Gross profit	31.0	28.0	—	1.8	1.2	62.0	2.3	64.4	
	SG&A expenses less R&D costs	15.2	17.2	5.2	1.4	0.2	39.2	1.5	40.6	
	<b>Income (loss) of Segment</b>	15.9	10.8	(5.2)	0.4	1.0	22.9	0.9	23.7	
	R&D costs							14.5	0.2	14.7
	Operating income							8.4	0.6	9.0
Change	Net sales (Sales to customers)	(5.0)	3.8	—	1.8	(0.1)	0.6	(0.4)	0.1	
	SG&A expenses less R&D costs	(0.7)	3.9	(2.6)	0.2	0.4	1.1	0.0	1.1	
	<b>Income (loss) of Segment</b>	(4.0)	0.7	2.6	1.6	(0.5)	0.5	(0.3)	0.2	
	R&D costs							0.5	(0.0)	0.5
	Operating income							(0.1)	(0.2)	(0.3)

- ※ 1. Excluding amortization of patent rights and goodwill, etc.  
 ※ 2. Amortization of patent rights and goodwill, etc.

Exchange Rate:

FY2013 1Q : 1US\$ = ¥ 98.8, 1RMB = ¥16.1  
 FY2014 1Q : 1US\$ = ¥102.2, 1RMB = ¥16.4

# 1Q Ordinary income & Net income

Billions of yen

	FY2013 1Q	FY2014 1Q	Change	
			Value	Percentage(%)
Operating Income	9.0	<b>8.7</b>	(0.3)	(3.7)
Non-operating income and expenses	0.5	<b>0.9</b>	0.4	
Ordinary income	9.5	<b>9.6</b>	0.1	0.6
Extraordinary income	—	<b>1.7</b>	1.7	
Compensation income for damage	—	<b>1.7</b>		
Extraordinary loss	1.0	<b>0.1</b>	(0.9)	
Business structure improvement expenses	0.6	<b>0.1</b>		
Impairment loss	0.4	—		
Income taxes	3.7	<b>5.4</b>	1.7	
Net income	4.8	<b>5.8</b>	0.9	19.7



# Revised Financial Forecasts for FY2014

Billions of yen

	FY2014 2Q			FY2014		
	Previous forecasts	Revised forecasts	Change	Previous forecasts	Revised forecasts	Change
Net sales	178.0	178.0	0.0	352.0	352.0	0.0
Cost of sales	51.5	<b>51.0</b>	<b>(0.5)</b>	102.5	<b>100.0</b>	<b>(2.5)</b>
Gross profit	126.5	<b>127.0</b>	<b>0.5</b>	249.5	<b>252.0</b>	<b>2.5</b>
SG&A expenses	114.5	<b>115.0</b>	<b>0.5</b>	229.5	<b>232.0</b>	<b>2.5</b>
SG&A expenses less R&D costs	82.0	<b>82.5</b>	<b>0.5</b>	159.5	<b>162.0</b>	<b>2.5</b>
R&D costs	32.5	32.5	0.0	70.0	70.0	0.0
Operating income	12.0	12.0	0.0	20.0	20.0	0.0
Ordinary income	11.5	11.5	0.0	19.0	19.0	0.0
Net income	6.3	<b>11.0</b>	<b>4.7</b>	12.0	<b>12.0</b>	0.0
EBITDA	21.0	21.0	0.0	38.0	38.0	0.0

# Outline of Revised Forecast for FY2014

## ■ **Net Sales**: Forecast of some products have been revised.

### ● Japan segment: Revised down 6 billion yen

- ✓ Forecast for long-listed products was reduced down due to stronger-than-expected impact from generics.

• AMLODIN <sup>®</sup>	¥22.4B	⇒	20.0	(2.4)
• GASMOTIN <sup>®</sup>	11.4		10.5	(0.9)
• PRORENAL <sup>®</sup>	11.6		10.5	(1.1)

### ● North America segment: Revised up 5 billion yen

- ✓ LATUDA<sup>®</sup> growing higher, Respiratory products are downward

• LATUDA <sup>®</sup>	¥61.0B	⇒	72.0	+11.0
• XOPENEX <sup>®</sup>	9.2		6.8	(2.4)
• ciclesonide (3 products)	9.3		5.9	(3.4)

### ● China: 2.3 billion yen up    Others: 1.3 billion yen down

• MEROPEN <sup>®</sup> (China)	¥10.6	⇒	13.0	+2.4
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## ■ **Expenses**: Sales & marketing cost has been revised up. Operating income is unchanged.

## ■ **Net Income**: 2Q forecast revised up ¥6.3B ⇒ **¥11.0**

- ✓ Extraordinary income (Sale of idle real estate) is expected to occur in 2Q, rather than in 3Q or later as originally assumed. Full year forecast of net income is unchanged.

# Development Pipeline (1) (as of July 30, 2014)

## Psychiatry & Neurology Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
LATUDA® (SM-13496)	lurasidone hydrochloride	Schizophrenia	Taiwan				
		Schizophrenia	Japan / China				
		Bipolar I depression, Bipolar maintenance	Japan				
		(New indication) Bipolar maintenance	U.S. / Europe, etc.				
		(New indication) MDD with mixed features	U.S. / Europe, etc.				
APTIOM® (SEP-0002093)	eslicarbazepine acetate	Epilepsy- Adjunctive therapy	Canada				
		(New indication) Epilepsy- Monotherapy	U.S.				
LONASEN®	blonanserin	Schizophrenia	China				
		(Addition of pediatric usage) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
AS-3201	ranirestat	Diabetic neuropathy	Japan				
EPI-743	TBD	Leigh syndrome	Japan				※1
SEP-225289	dasotraline	Attention-deficit hyperactivity disorder (ADHD)	U.S.				
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
DSP-2230	TBD	Neuropathic pain	U.K. / U.S.				
SEP-363856	TBD	Schizophrenia	U.S.				

※1 Phase II/III study

◆ Approved / Preparing for launch

Revisions since the previous announcement are in red.

# Development Pipeline (2) (as of July 30, 2014)

## Cancer Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
CALSED® (Brand name in Japan)	amrubicin hydrochloride	Small cell lung cancer	China				
BBI608	TBD	Colorectal cancer (Monotherapy) (Global clinical trial)	U.S. / Canada / Japan, etc.	Accrual of new patients has been stopped			
		Gastric cancer, Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical trial)	U.S. / Canada				
		Colorectal cancer (Combination therapy)	U.S. / Canada				
		Solid tumors (Combination therapy)	U.S. / Canada			※1	
		Gastrointestinal cancer (Combination therapy)	U.S. / Canada				
		Gastric cancer (Combination therapy)	Japan				
		BBI503	TBD	Solid tumors (Monotherapy)	U.S. / Canada		
Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, Gastrointestinal stromal tumor (Monotherapy)	Canada						
WT4869	TBD	Myelodysplastic syndromes	Japan		※2		
		Solid tumors	Japan				
WT2725	TBD	Solid tumors, Hematologic cancers	U.S.				
		Solid tumors	Japan				

※1 Phase II of Phase I/II study

※2 Phase I of Phase I/II study

# Development Pipeline (3) (as of July 30, 2014)

## Respiratory Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
SUN-101	glycopyrrolate bromide	Chronic obstructive pulmonary disease (COPD)	U.S.				
DSP-3025	TBD	Bronchial asthma/Allergic rhinitis	Japan				

## Cardiovascular / Diabetes Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
METGLUCO®	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes	Japan				
SUREPOST®	repaglinide	(New indication) Type 2 diabetes (All combination therapies including DPP-4 inhibitors)	Japan				

## Other Areas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				

# BBI608 - Clinical development status

## ■ U.S., Canada, Japan, etc.

- **Colorectal cancer (Monotherapy)**

Further enrollment of new patients was stopped and all study drug was discontinued in patients in May 2014.

Data analysis of the approximately 280 patients (who have been enrolled in this study) in progress  
⇒ Development plan of Colorectal cancer (Monotherapy) to be considered based on the result of this clinical study.

## ■ U.S., Canada

- **Gastric cancer/ Gastro-esophageal junction adenocarcinoma (Combination therapy)**

Phase III in progress (initiated in 1Q 2014)

- **Colorectal cancer (Combination with Cetuximab, Panitumumab, or Capecitabine)**

Phase II in progress (initiated in 1Q 2012)

- **Solid tumors (Combination with paclitaxel)**

Phase II of Phase I / II in progress (initiated in 2Q 2013)

Phase II : Ovarian cancer, Breast cancer, Non-small cell lung cancer, Melanoma, etc.

- **Gastrointestinal cancer (Combination with FOLFOX\*<sup>1</sup>, FOLFIRI\*<sup>3</sup> and Bevacizumab, CAPOX\*<sup>2</sup>, FOLFIRI\*<sup>3</sup>, FOLFIRI\*<sup>3</sup> and Bevacizumab, or Regorafenib)**

Phase I in progress (initiated in 4Q 2013)

\*1: FOLFOX (Combination with Fluorouracil, Leucovorin, Oxaliplatin)

\*2: CAPOX (Combination with Capecitabine, Oxaliplatin)

\*3: FOLFIRI (Combination with Fluorouracil, Leucovorin, Irinotecan)

## ■ Japan

- **Gastric cancer (Combination with paclitaxel)**

Phase I in progress (initiated in 4Q 2013)

Revisions since the previous announcement are in red.

# BBI503 - Clinical development status

## ■ U.S., Canada

- **Solid tumors (Monotherapy)**

Phase II of Phase I / II in progress (initiated in 2Q 2014)

Phase II : Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.

## ■ Canada

- **Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, Gastrointestinal stromal tumor (Monotherapy)**

Phase II in progress (initiated in 2Q 2014)

# Disclaimer Regarding Forward-looking Statements

The statements made in this presentation material are forward-looking statements based on management's assumptions and beliefs in light of information available up to the day of announcement, and involve both known and unknown risks and uncertainties.

Actual financial results may differ materially from those presented in this document, being dependent on a number of factors.

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