Sumitomo Pharma (4506)

Key takeaways from analyst meeting with president and vice president

Overweight

4506.T, 4506 JP
Price (09 Sep 26):¥1,545
Price Target (Dec-27):¥2,700

Japan Equity Research
Biotechnology & Pharmaceuticals/ Medical Technologies & Services

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We hosted a meeting between Sumitomo Pharma President Toru Kimura and Vice President Motoyuki Sakai and investors on September 8. Discussions with management enabled us to confirm the current cash flow generation capability and high management expectations for enzomenib and nuvisertib, giving us a positive impression. Management estimates the impact on Orgovyx from a future IRA-based drug price cut at about 10%, smaller than our estimate. We believe Sumitomo Pharma's earnings base through Orgovyx and Gemtesa is solid, and expect its market valuation to rise further if enzomenib and nuvisertib emerge more clearly as growth drivers as their development progresses. We also view SMP-3124, which uses the liposomal nanomedicine technology, and fH1/DSP-0546LP, a universal influenza vaccine using TLR7 adjuvant (DSP-0546LP), as important pipeline assets not recognized by investors that could create medium- to long-term upside depending on future development trends. We outline main points of the discussion below.

- **Long-term growth outlook:** While the company believes discussion of specific figures is premature since it has not yet released a medium-term plan, it targets combined Orgovyx and Gemtesa sales of ¥400 billion in the first half of the 2030s and is on track achieve it. It expects Orgovyx and Gemtesa to remain the main driver of sales and profit five years from now, but expects to file for approval of enzomenib and nuvisertib and for a full approval of Amchepry by around that time. It expects oncology products to launch and become the second driver in 10 years. It expects the price of Gemtesa to decline by about 10% due to the IRA impact. It sees a high likelihood of growth in five and 10 years. In 15 years, Orgovyx will reach the loss of exclusivity (LOE) around 2038, but the company expects oncology products and Amchepry to grow. **Confidence about growth:** Management said data on enzomenib made it more confident. It said that concerns in FY2025 (the likelihood of obtaining data on enzomenib, continuation of development and patient enrollment under fierce competition, financial uncertainty about securing a development budget) were eliminated by strong progress in programs, including those targeting NPM1 mutation, solid FY2026 earnings, ¥98 billion raised through a public offering, and recently obtained data, increasing its confidence.
- **Enzomenib's potential:** Sumitomo Pharma believes enzomenib can compete with the two preceding products (Revuforj, Komzifti) in efficacy and safety. Compared with Johnson & Johnson's bleximenib, while noting that its comments are based on limited data that are publicly available, management said that efficacy and safety look comparable, but given bleximenib's protocol calling for dose escalation, the need for pretreatment to reduce differentiation syndrome, and instances of death, it believes it can differentiate enzomenib for its ease of use. It believes the reason enzomenib does not cause much differentiation syndrome or drug-induced QT prolongation lies in its compound structure. Regarding the risk of drug resistance caused by menin E368 mutations, management said the incidence rate of such resistance looks relatively low based on internal data. The company has already enrolled enough patients needed for interim analysis of the study targeting KMT2A rearrangement, and expects to obtain top-line results in early 2027. It expects

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to disclose data from before interim analysis, including three- to four-months data, at the American Society of Hematology (ASH) annual meeting in December. It said it has set high internal standards for data not only for approval but also for commercial success.

- **Nuvisertib's potential:** Sumitomo Pharma said nuvisertib's key feature is that is causes no hematologic toxicity. Sales of momelotinib grew rapidly in 2025 as its use spread. However, momelotinib's efficacy is not necessarily high, so the company plans to differentiate nuvisertib with its lack of hematologic toxicity, and positions it as a drug to supplement momelotinib's efficacy. It expects the prescription of a JAK inhibitor followed by momelotinib to become established as the standard treatment of myelofibrosis (MF), and since developing nuvisertib as monotherapy would make patient choices more complicated, it plans to develop it mainly for combination with momelotinib. It also expects nuvisertib's effect to improve anemia through ACVR1 inhibition to be appealing to MF patients. Since the current first-line drug is ruxolitinib, various patterns will become a possibility once data on combination with ruxolitinib are obtained, including combination use with ruxolitinib and with unspecified JAK inhibitors. While the company plans to discuss the Phase 3 design with potential partners, it will proceed with development without waiting for a decision on the partner to avoid trial delays.
- **Partnering strategy: Partnership strategy:** Sumitomo Pharma is not considering simply licensing out its assets as it aims to establish a marketing platform in oncology. It is excluding Europe because it does not have a marketing franchise there, seeking to establish a platform in the US and Japan. Its basic strategy is to split profit 50:50 with a partner, but it also sees the need to be mindful of detailed terms. It needs indication expansion to maximize its assets' potential, but since this also creates risks, it noted options including implementing only reliable indications in-house. It says it cannot predict whether it will form a partnership on enzomenib or nuvisertib first. It recognizes that investors are trying to measure the value of its assets based on whether or not it can form partnerships, viewing partnerships as a measure of future success. However, it explained that it has not completely ruled out developing assets in-house for as long as it can, depending on conditions on which it cannot compromise. **Reasons for assuming partnerships:** In 2025, Sumitomo Pharma viewed other companies' capabilities as prerequisites as it could not conduct in-house development or generate large profit without partnerships. However, its nature has changed so that it can achieve a lot independently and can decide whether or not it needs partnerships from the perspective of maximizing its own profit. **Enzomenib:** Sumitomo Pharma is at the stage of making inquiries to potential partners and does not plan to negotiate specific prices until interim analysis. It believes potential partners are also seeking to negotiate after seeing interim analysis data. If it obtains data that can be disclosed at ASH, it plans to resume partnership activities without waiting for the release of top-line data. **Nuvisertib:** The company said it might decide on a partner independently from the concomitant medication, so a partner will not be limited to GSK, which developed momelotinib.
- **Orgovyx: Milestones:** The final milestone from Pfizer is conditional on sales of $2.5 billion, but Sumitomo Pharma views this as a high bar to clear around 2030. However, there are several other thresholds before $2.5 billion, and it hopes to achieve them. Orgovyx's market share in oncology is only about 10%, so it sees significant room for growth. However, it also said that surgical removal is viewed as the basic treatment in oncology, and shrinking tumors tends to be emphasized more than reducing side effects. It thus sees a slight gap from Orgovyx's appeal of reducing tumor while controlling side effects, and is struggling to promote the drug on the marketing front. While the drug's growth rate in oncology is higher than in urology, the ultimate peak sales are unclear. **Risks:** Sumitomo Pharma views the Guarding US Medicare Against Rising Drug Costs (GUARD) Model as the biggest risk to Orgovyx sales, and expects a direct impact if it is implemented. While its policy priority seems to have declined, the company believes

some kind of action, such as an agreement to avoid being targeted, might become necessary if it is implemented. The company explained that it has not reached agreement with the US government on the most-favored-nation (MFN) drug pricing policy because it plans to monitor policy trends. It plans to prioritize collecting information in the near term. Its partner Pfizer has signed an agreement with the US government on MFN, but the agreement's framework does not apply to Orgovyx since it was approved under the company name of Sumitomo Pharma US.

- **Gemtesa:** Gemtesa has become the top drug in the market including generics after volume has risen sharply recently, showing the fastest growth rate, but Sumitomo Pharma has not identified any factors behind this rapid growth yet. The gross-to-net price difference (GtN) was larger than the company had expected because it received payments without rebates from prescriptions written when the drug was not covered by insurance, and while it expects GtN to decline as insurance coverage kicks in, it also hopes this impact will last for a long time. The company is confident that its patents are very strong, but did not disclose details, citing pending lawsuits. It does not expect much impact from IRA-based price renegotiations since Gemtesa belongs to the urology area, where prices are low, and views competition at the time of generic entry as the topic of focus.
- **IRA impact:** Orgovyx will be subject to IRA-based price negotiations if sales grow, and the company assumes the price will fall at some point over the medium term. It expects the price to fall by about 10%, and has already factored this impact into the ¥400 billion sales guidance noted above. It sees virtually no impact on Gemtesa since it is an urology drug with a low price.
- **Capital allocation: Debt repayment:** Sumitomo Pharma said it has been repaying debts faster than expected. It expects to be able to shift to net cash by end-FY2026, while also repaying subordinated debt steadily. **Growth investment:** The company plans to manage its finances with discipline and allocate any excess funds to growth investments with discipline. While it has clearer prospects for repaying debt, it also sees the need to watch the US political situation before making growth investments. It believes when to use capital is essential, and showed a willingness to make growth investments when doing so is vital. It sees two main purposes of investments: (1) strengthening Japan, which is the main market (with small amounts of capital) and (2) in-licensing to use the marketing infrastructure established through Orgovyx and Gemtesa. It has conducted no in-house research in the areas of Orgovyx or Gemtesa, so this is another possibility. **Shareholder returns:** Sumitomo Pharma has already indicated the possibility of resuming dividend payments in 2Q, and will consider starting with a small amount. Overseas investors tend not to expect dividends and prefer improving enterprise value through R&D, but some Japanese investors seek dividends from listed companies, so management hopes to strike the right balance. Management said it is premature to discuss when its dividend payout ratio will return to the 20% level of the past, and it has made no internal decision on whether to use the dividend payout ratio as a benchmark, but said it plans to finalize its policy by end-FY2026.
- **New medium-term plan:** Sumitomo Pharma aims to finalize its next medium-term plan by end-FY2026, but is internally discussing the timing, including a delay into April or May 2027. It plans to release the new medium-term plan and use this as a basis for earnings estimates when the likelihood of partnerships on two oncology drugs rises to a certain level, without waiting for final agreements. It explained that the main points of discussion include growth investment, solidifying recent improvements, and balancing Japan and the US (whether to strengthen the Japanese market, where earnings are weak because of Japan's drug price policy, or to allocate capital to US development given a significant difference in product mix between Japan and the US).
- **Relationship with parent company:** When Sumitomo Pharma had a public offering (to raise ¥98 billion), parent Sumitomo Chemical announced that it did not plan to buy the shares, and Sumitomo Pharma decided on the number of shares issued based on the large

impact becoming Sumitomo Chemical's equity-method affiliate would have at this stage. It plans no additional share offering since it just had an offering this year. The offering has lowered Sumitomo Chemical's ownership ratio of voting rights, but Sumitomo Pharma said that consolidation is based on the criteria of control, including control in real terms and the ratio of voting at the general meeting of shareholders, and it does not believe directors dispatched from Sumitomo Chemical have a direct impact.

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Investment Thesis, Valuation and Risks

Sumitomo Pharma (4506) *(Overweight; Price Target: ¥2,700)*

Investment Thesis

The investment thesis for Sumitomo Pharma revolves around how much EPS can expand through the sales growth of Gemtesa, Orgovyx, and Myfembree, as well as the potential of pipeline products including enzomenib and nuvisertib.

Valuation

We calculate our end-December 2027 price target of ¥2,700 using a DCF model based on our estimates for FY2028–37, assuming a terminal growth rate of 0% and WACC of 8.8%. Our price target of ¥2,700 works out to 7.2x our FY2028 EPS forecast of ¥374 and 22.6x our FY2032 EPS forecast of ¥120. We forecast an EBITDA CAGR of –24.8% in FY2028–32 and –11.5% in FY2028–37.

DCF Model

¥mn

	FY28E	FY29E	FY30E	FY31E	FY32E	FY33E	FY34E	FY35E	FY36E	FY37E
Profit before tax	186,300	125,600	77,300	79,300	76,700	84,200	85,700	93,400	100,300	79,900
Depreciation and Amortization	20,400	20,400	20,400	20,400	20,400	20,400	20,400	20,400	20,400	20,400
Impairment Loss	0	0	0	0	0	0	0	0	0	0
Decrease (Increase) in Working Capital	-25,312	10,671	33,833	-2,981	-17,427	-11,008	-7,438	-4,518	-3,211	23,482
Income Taxes Paid	-18,630	-12,560	-18,570	-23,790	-23,010	-25,260	-25,710	-28,020	-30,090	-23,970
Income Taxes Paid	0	0	0	0	0	0	0	0	0	0
Capital Investment	-11,000	-11,000	-11,000	-11,000	-11,000	-11,000	-11,000	-11,000	-11,000	-11,000
Others	0	10,000	0	0	0	0	0	0	0	0
FCC	151,758	143,111	101,963	61,929	45,663	57,332	61,952	70,262	76,399	88,812
Discount rate	1.1	1.2	1.3	1.4	1.5	1.7	1.8	2.0	2.1	2.3
Present Value	139,469	120,873	79,145	44,178	29,936	34,543	34,304	35,756	35,731	38,173

Assumptions	
Shares Outstanding (excluding treasury shares,m)	449
Tax rate	22.8%
Terminal growth rate	0.0%
Risk-free rate	2.9%
Risk premium	4.6%
β	1.6
Cost of equity	10.0%
Cost of debt	0.3%
WACC	8.8%

Terminal Value	433,247
Net Present Value	592,109
+ Cash & Deposits at term end	214,152
+ Other adjustment items	59,588
=Enterprise value	1,299,096
-Interest-bearing debt	90,000
=Equity value	1,209,096
Share Price(¥)	2,700

WACC \ Terminal growth rate	0	-1.5%	-1.0%	-0.5%	0.0%	0.5%	1.0%	1.5%
7.3%	2,920	2,980	3,060	3,140	3,240	3,360	3,490	
7.8%	2,780	2,840	2,900	2,970	3,060	3,150	3,260	
8.3%	2,660	2,710	2,770	2,830	2,900	2,970	3,060	
8.8%	2,550	2,600	2,640	**2,700**	2,750	2,820	2,890	
9.3%	2,460	2,490	2,530	2,580	2,630	2,680	2,750	
9.8%	2,370	2,400	2,440	2,470	2,520	2,560	2,620	
10.3%	2,290	2,320	2,350	2,380	2,420	2,460	2,500	

Source: Company data, J.P. Morgan estimates

Risks to Rating and Price Target

Upside Scenario to Target Price/Rating

- Sales of Orgovyx, Myfembree, and Gemtesa exceed the stock market's expectations
- Development progress of pipeline products including enzomenib and nuvisertib

Downside Scenario to Target Price/Rating

- Weak market penetration by Orgovyx, Myfembree, and Gemtesa
- Clinical trial failures or delays

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