COMPANY UPDATE

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Innovation Team

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Next Biomedical (389650)

Earnings to grow; pay attention to news

- Next Biomedical has been profitable since 2Q25 thanks to solid sales of Nexpowder. The company also enjoys strong R&D momentum, with development of next-generation pipeline drugs (Nexsphere-F and Nexsphere) well underway.

(The Korean version of the report was published on Nov 28)

WHAT'S THE STORY?

Nexpowder sales growing: Next Biomedical reported 3Q sales of KRW4.9b (up 125% y-y and 24.2% q-q) and an operating profit of KRW0.4b (turning positive y-y), led by strong exports of Nexpowder (an endoscopic hemostatic salvage therapy; Nexpowder exports of KRW4.3b in 3Q, up 151% y-y and 24.6% q-q), extending the operating profit trend seen since 2Q. The company has been shipping USD0.4m-0.5m worth of Nexpowder to the US and Europe (combined) per month via global partner Medtronic. It is also selling the drug in Japan, where the drug has been listed and covered since September. In its 2QFY26 earnings presentation material (fiscal year ends March), Medtronic mentioned the possibility of its endoscopy business enjoying high single-digit growth that quarter thanks to Nexpowder. After completing post-marketing clinical trials on Nexpowder (the trial is set to finish in Aug 2026; the trials were begun by Medtronic in 2024 in the US with 278 patients), and based on the clinical trial results, Next Biomedical expects the drug to be included in major gastroenterology societies' guidelines for endoscopic hemostasis.

(Continued on the next page)

SUMMARY FINANCIAL DATA

	2021	2022	2023	2024
Revenue (KRWb)	2	3	5	10
Operating profit (KRWb)	-7	-6	-5	-4
Net profit (adj) (KRWb)	-17	-6	-8	3
EPS (adj) (KRW)	-2,525	-838	-1,089	386
EPS (adj) growth (% y-y)	nm	nm	nm	nm
EBITDA margin (%)	-288.3	-189.8	-97.5	-32.3
ROE (%)	-201.5	-237.4	244.4	14.6
P/E (adj) (x)	n/a	n/a	n/a	106.1
P/B (x)	n/a	n/a	n/a	7.3
EV/EBITDA (x)	n/a	n/a	n/a	n/a
Dividend yield (%)	n/a	n/a	n/a	0.0

Source: Company data, Samsung Securities

AT A GLANCE

Not Rated

Target price	n/a
Current price	KRW90,600
Market cap	KRW743.23b / USD507.12m
Shares (float)	8,203,886 (69.5%)
52-week high/low	KRW78,500/KRW35,500
Avg daily trading value (60-day)	KRW8.0b/ USD5.5m

ONE-YEAR PERFORMANCE

	1M	6M	12M
Next Biomedical (%)	45.3	102.1	126.3
Vs Kosdaq (%pts)	41.7	65.2	64.2

SAMSUNG vs THE STREET

No of estimates	4
Target price	93,000
Recommendation	4.0

※ Rating: 4 < → BUY, 3 = HOLD, 2 > → SELL

Developing next-generation pipeline drugs: Meanwhile, the company began registering patients for its US Phase I clinical trial for Nexsphere-F (a gelatin-based hydrophilic material for endovascular embolization) in Oct 2025. Thanks to its winning breakthrough device designation (BDD) from the FDA in March, and further thanks to the FDA approval for CMS IDE category B and FDA TAP approval in May (events that reduced costs at clinical trial-participating hospitals and shortening the trial approval-commercialization-reimbursement coverage process), Next Biomedical now plans to recruit more patients in 1H26 and win trial approval in 2027. It also intends to choose a US partner before patient recruitment has been completed. It is conducting post-marketing clinical trials on Nexsphere-F in Korea and Europe (regions where the drug has been approved). As the clinical trials should prove the drug's efficacy as an arthritis pain treatment, the drug's applications should be widened upon the release of the clinical trial results. Moreover, the company lately had an FDA pre-submission meeting for Nexsphere (its liver cancer & uterine myoma treatment; already sold in Korea). After meeting drug bioequivalence testing requirements, it should seek FDA 510(k) approval for the drug in 4Q25, with a goal of winning approval in 2026.

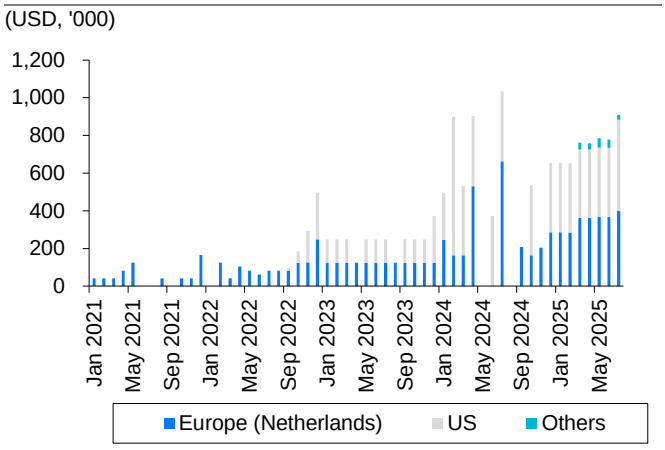
Financials: The company has a net cash position of KRW35b (as of end-3Q). With its cash holdings, the company can finance the costs of US clinical trials for Nexpowder and European clinical trials for Nexsphere-F.

Next Biomedical: Performance and consensus

(KRWb)	2023	2024	2025E	2026E	1Q24	2Q24	3Q24	4Q24	1Q25	2Q25	3Q25	4Q25E
Sales	**4.9**	**9.5**	**18.1**	**29.4**	**2.4**	**2.8**	**2.2**	**2.2**	**3.8**	**4.0**	**4.9**	**5.4**
Nexpowder	4.3	8.3			2.1	2.3	1.7	2.0	3.1	3.4	*4.3*	
Nexsphere	0.6	0.8							0.3	0.3	*0.3*	
Nexsphere-F	0.0	0.5							0.3	0.2	*0.3*	
Others	0.0	0.0			0.3	0.5	0.5	0.2	0.0	0.0	*0.1*	
Gross profit	2.1	5.8			1.4	1.7	1.3	1.3	2.4	2.8	3.6	
Operating profit	-5.2	-3.6	-0.8	4.5	-0.6	-0.9	-1.0	-1.1	-0.7	0.0	0.4	-0.6
Net profit(controlling)	-7.5	2.9	-1.3	5.1	-0.4	-0.7	3.8	0.1	-0.4	-0.9	1.1	0.0
Chg (% y-y)												
Sales		*95.5*	*89.3*	*62.5*					*59.2*	*44.2*	*125.1*	*144.0*
Nexpowder		*93.4*							*48.4*	*49.0*	*151.3*	
Nexsphere		*34.0*										
Nexsphere-F		*3337.7*										
Others		*-16.0*							*-94.7*	*-90.4*	*-89.4*	
Gross profit		*176.1*							*71.3*	*63.7*	*165.0*	
Operating profit		*-31.6*	*-76.7*	*-640.0*					*18.5*	*-102.3*	*Turned pos*	*-46.1*
Net profit(controlling)		*-138.0*	*-143.7*	*-504.0*					*18.5*	*32.2*	*Turned pos*	*-100.0*
Margin (%)												
Gross profit	**43.2**	**61.0**	**0.0**	**0.0**	***60.3***	***62.8***	***61.5***	***59.1***	**64.9**	**71.3**	**72.5**	***0.0***
Operating profit	**-107.1**	**-37.5**	**-4.6**	**15.3**	***-23.8***	***-32.3***	***-46.0***	***-50.0***	**-17.7**	**0.5**	**7.5**	**-11.0**
Net profit (controlling)	**-154.1**	**30.0**	**-6.9**	**17.2**	***-15.0***	***-24.8***	***171.3***	***6.4***	**-11.1**	**-22.7**	**21.5**	**0.0**

Note: Estimates are based on consensus
Source: Quantiwise, Samsung Securities

Exports of sterile absorbable surgical hemostatics



Note: HS Code 3006.10.4000 (Yeonsu-gu, Incheon), assumed to be Nexpowder export data
Source: TRASS, Samsung Securities

Next Biomedical: Clinical status of major products

	Major clinical trials	Remarks
Nexpowder	Two clinical trials ongoing after launch 1) Primary treatment (US, 278 patients) NCT06188585 2) Prevention purposes for colon (Europe, 304 people) NCT05247515	Medtronic leads; in the case of the first clinical trial, the goal is to be listed as a standard treatment for endoscopic bleeding (to be completed on Aug 2026)
Nexsphere-F	Clinical trials to begin in 3Q25 (RESORB, 126 in the US) NCT06872567 Large-scale post-marketing clinical trial planned in Europe (1H26, 500 patients)	To secure US partners in 1H26 Aims to expand indications to include sports arthritis Mar 2025, designated FDA BDD May 2025, designated CMS IDE Category B May 2025, FDA TAP (regulatory science consultation and strategic support)
Nexphere (Uterine fibroids/Liver cancer)	Additional clinical trials expected in 2026 if needed	FDA 510(k) submission expected in 4Q25 Aims to be approved in 2026

Source: Samsung Securiteis

Income statement

Year-end Dec 31 (KRWb)	2020	2021	2022	2023	2024
Sales	**2**	**2**	**3**	**5**	**10**
Cost of goods sold	2	3	3	3	4
Gross profit	**0**	**-1**	**0**	**2**	**6**
Gross margin (%)	0.9	-27.6	10.2	43.2	61.0
SG&A expenses	5	6	6	7	9
Operating profit	**-5**	**-7**	**-6**	**-5**	**-4**
Operating margin (%)	-205.1	-307.4	-206.4	-107.1	-37.5
Non-operating gains (losses)	**-0**	**-10**	**0**	**-2**	**6**
Financial profit	0	0	1	1	7
Financial costs	0	10	0	3	1
Equity-method gains (losses)	0	0	0	0	0
Other	-0	0	-1	0	0
Pre-tax profit	**-5**	**-17**	**-6**	**-8**	**3**
Taxes	0	0	0	0	0
Effective tax rate (%)	0.0	0.0	0.0	0.0	0.0
Profit from continuing operations	-5	-17	-6	-8	3
Profit from discontinued operations	0	0	0	0	0
Net profit	**-5**	**-17**	**-6**	**-8**	**3**
Net margin (%)	-215.1	-734.1	-205.1	-154.1	30.0
Net profit (controlling interests)	-5	-17	-6	-8	3
Net profit (non-controlling interests)	0	0	0	0	0
EBITDA	-4	-7	-5	-5	-3
EBITDA margin (%)	-187.9	-288.3	-189.8	-97.5	-32.3
EPS (parent-based) (KRW)	-783	-2,525	-838	-1,089	386
EPS (consolidated) (KRW)	-783	-2,525	-838	-1,089	386
Adjusted EPS (KRW)*	-783	-2,525	-838	-1,089	386

Balance sheet

Year-end Dec 31 (KRWb)	2020	2021	2022	2023	2024
Current assets	**9**	**24**	**18**	**18**	**47**
Cash & equivalents	7	22	3	4	5
Accounts receivable	0	0	0	1	2
Inventories	2	1	2	2	3
Other current assets	0	0	12	11	38
Fixed assets	**15**	**16**	**15**	**12**	**12**
Investment assets	3	4	3	0	0
Tangible assets	12	12	12	11	11
Intangible assets	0	0	0	0	0
Other long-term assets	0	0	0	0	0
Total assets	**24**	**40**	**32**	**30**	**59**
Current liabilities	**12**	**13**	**31**	**34**	**12**
Accounts payable	0	0	0	0	0
Short-term debt	4	6	6	6	6
Other current liabilities	8	7	25	28	6
Long-term liabilities	**1**	**22**	**1**	**2**	**2**
Bonds & long-term debt	0	0	1	1	1
Other long-term liabilities	1	22	1	1	1
Total liabilities	**13**	**35**	**32**	**36**	**14**
Owners of parent equity	**11**	**5**	**-0**	**-6**	**45**
Capital stock	1	3	3	3	4
Capital surplus	23	61	61	62	107
Retained earnings	-13	-60	-65	-73	-70
Other	-0	1	1	2	4
Non-controlling interests' equity	**0**	**0**	**0**	**0**	**0**
Total equity	**11**	**5**	**-0**	**-6**	**45**
Net debt	3	10	16	20	-15

Cash flow statement

Year-end Dec 31 (KRWb)	2020	2021	2022	2023	2024
Cash flow from operations	**-3**	**-5**	**-8**	**-4**	**-1**
Net profit	-5	-17	-6	-8	3
Non-cash profit and expenses	1	11	0	4	-4
Depreciation	0	0	0	0	0
Amortization	0	0	0	0	0
Other	1	10	-0	4	-4
Changes in A/L from operating activities	0	0	-2	-1	-1
Cash flow from investments	**-4**	**-1**	**-11**	**4**	**-26**
Change in tangible assets	-1	-0	-0	-0	-0
Change in financial assets	-3	2	-12	2	-10
Other	-0	-3	1	2	-16
Cash flow from financing	**3**	**22**	**0**	**1**	**28**
Change in debt	3	22	-1	3	-23
Change in equity	0	40	0	1	46
Dividends	0	0	0	0	0
Other	-0	-40	1	-3	5
Change in cash	-4	15	-19	1	1
Cash at beginning of year	11	7	22	3	4
Cash at end of year	7	22	3	4	5
Gross cash flow	**-3**	**-6**	**-6**	**-3**	**-1**
Free cash flow	**-4**	**-6**	**-8**	**-4**	**-2**

Financial ratios

Year-end Dec 31	2020	2021	2022	2023	2024
Growth (%)					
Sales	182.3	0.3	23.3	74.7	95.5
Operating profit	nm	nm	nm	nm	nm
Net profit	nm	nm	nm	nm	nm
Adjusted EPS**	nm	nm	nm	nm	nm
Per-share data (KRW)					
EPS (parent-based)	-783	-2,525	-838	-1,089	386
EPS (consolidated)	-783	-2,525	-838	-1,089	386
Adjusted EPS**	-783	-2,525	-838	-1,089	386
BVPS	1,841	743	-37	-846	5,588
DPS (common)	0	0	0	0	0
Valuations (x)					
P/E***	n/a	n/a	n/a	n/a	106.1
P/B***	n/a	n/a	n/a	n/a	7.3
EV/EBITDA	n/a	n/a	n/a	n/a	n/a
Ratios (%)					
ROE	-35.2	-201.5	-237.4	244.4	14.6
ROA	-19.5	-51.9	-16.0	-24.3	6.5
ROIC	-37.6	-58.3	-44.6	-36.6	-23.8
Payout ratio	0.0	0.0	0.0	0.0	0.0
Dividend yield (common)	n/a	n/a	n/a	n/a	0.0
Net debt to equity	28.8	191.5	-6,361.3	-331.9	-32.7
Interest coverage (x)	-19.3	-4.9	-16.0	-9.1	-6.9

Note: *Excluding one-off items
**Fully diluted, excluding one-off items
***From companies subject to equity-method valuation

Source: Company data, Samsung Securities

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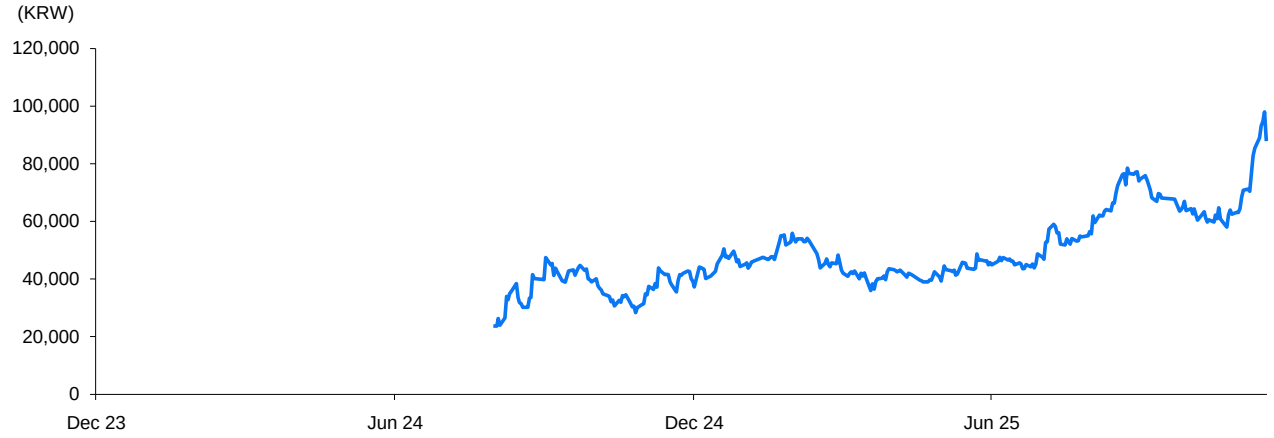

Rating changes over past two years (adjusted share prices)

Date	2025/12/9
Recommendation	Not Rated
Target price (KRW)	n/a
Gap* (average)	
(max or min)**	

Note: * [(average, maximum, or minimum share price over duration of target price minus target price) / target price] x 100%
** Maximum/minimum share price if new target is higher/lower than market close on the business day prior to target price change

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Percentage of ratings in 12 months prior to 2025.09.30

BUY(83.5%)·HOLD(16.5%)·SELL(0%)

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