Spruce Biosciences, Inc. (SPRB)
Covering Analyst: Adam Eminger
Current Rating: **BUY**

Price date: 07/03/2026
Latest Closing Price: $52.51
Market Cap: $144.11M
52-Week Range: $7.26 (pre-reverse-split low) – $240.00
Next Catalyst: FDA application, Q4 2026

Discovery Insights and Beliefs:

In your own words, describe what this company does and how it makes money?

Spruce is a small drug company with one product. That product is a treatment for a rare and fatal childhood disease called Sanfilippo Syndrome Type B, which doctors also label MPS IIIB. Children born with this disease are missing an enzyme that their brain cells need, so waste builds up in the brain and slowly destroys it. Most of these children do not live past their late teens, and today there is no approved treatment of any kind. Spruce's drug, which it calls TA-ERT, is a manufactured copy of that missing enzyme. Because the enzyme cannot travel from the bloodstream into the brain on its own, the drug is infused once a week through a small port that delivers it straight into the fluid around the brain.

Spruce has no sales yet. The whole company is an effort to get this one drug approved and onto the market, and if that happens it will make money in two ways. The first is by selling the drug, and treatments for diseases this rare carry very high annual prices because the number of patients is tiny and there is no competition. The second is a one-time bonus from the government. When the FDA approves a drug for a rare disease, it hands the company a voucher that can be sold to a larger drugmaker for cash, usually around $150 million. Spruce did not invent this drug. It bought the rights cheaply in late 2024 when the previous owner went bankrupt. Spruce now pays a slice of any future sales to BioMarin, the company that holds the original patents. Spruce's first drug failed and the stock collapsed, forcing the company to do a reverse split that bundled many old shares into one just to keep its price high enough to stay listed. TA-ERT is the fresh start, and it is the whole story.

Why is this a great investment idea?

The simple version is that the stock trades for far less than the drug appears to be worth. The single biggest risk in any drug investment is the risk that regulators say no. That risk has already come down more than the price reflects. My model puts fair value at about $131 a share, and the stock recently traded near $52, so there is high upside on the table.

The reason I am willing to back it is that the FDA has already shown its hand. Normally a company must run long and expensive trials proving a drug helps patients live longer or better before it can be approved. The FDA agreed that Spruce can instead rely on a marker in the spinal fluid that falls when the drug is working, which means the agency told Spruce that if this marker moves the right way it is good enough to support approval. The FDA confirmed this twice, first

in 2024 and again in late 2025. The drug also carries four regulatory designations from the FDA: Rare Pediatric Disease, Fast Track, Breakthrough Therapy, and Orphan Drug. It holds Orphan Drug status in the EU as well. Breakthrough Therapy is the most significant. It commits the FDA to work closely with Spruce throughout the review, which reduces the chance of late-stage surprises. Orphan Drug status locks out competition for seven years in the United States after approval and ten years in the EU. Spruce plans to file its formal application in the final months of 2026, with a possible launch in the middle of 2027. This would be the first and only treatment for a disease that otherwise kills children. A deadly illness with no other option, a regulator that is already on board, and a clear finish line are what make the potential reward much larger than the risk.

Why is this a good business?

Treating a rare disease is one of the steadiest businesses in all of medicine, and this drug fits the pattern perfectly. There is no rival product, the disease lasts a lifetime so patients stay on treatment for years, and because only a handful of specialist hospitals treat these children Spruce can reach almost the entire market with a small sales team rather than an army of representatives.

Price is what makes the economics work. My model assumes Spruce charges about $828,000 per patient each year in the United States, which sounds enormous but is normal for this category. This price is actually a discount to the price of Brineura, an approved drug for a similar rare childhood brain disease that I use throughout this report as the real-world benchmark. The costs are low once the drug is selling because making it runs about 18% on every dollar of sales and BioMarin takes roughly another 10% as its cut. On top of the regular sales, an approval delivers that one-time government voucher, which my model values at about $83 million after adjusting for the chance the drug fails. A small number of patients, a very high price, and low costs add up to a genuinely good business.

Why is it sustainable?

What protects this business over time is its evidence and its legal protection. Spruce has followed treated patients for five years and over that stretch the drug pushed the key disease marker back to normal or near-normal levels. It keeps part of the brain from shrinking the way it does in untreated children and helped slow the loss of thinking and learning skills, which is all measured against the known and grim course of the untreated disease. Five years of evidence in a disease that usually moves quickly is rare and hard for any competitor to argue with.

Being first and only matters a great deal here. An approved rare-disease drug receives years of market protection, and any company that wanted to challenge it would have to run its own multi-year studies from scratch. Families and doctors also do not walk away from the one treatment that is changing the course of the disease, so the customer base tends to stay put. It is first and only today, but it will not be alone forever. Gene therapy and other enzyme programs for Sanfilippo are in development, so I have not assumed this lasts indefinitely. My model builds in gradual price declines starting in 2037 as a cautious acknowledgement to that competition eventually arriving.

Why do their customers buy from them?

Spruce has no customers yet, so the real question is why patients, doctors, and insurers will choose this drug once it is approved. Families will choose it because it is the only treatment that

changes the disease, and the alternative is simply managing symptoms while the child declines. Doctors, who are clustered at a small number of specialist centers, will prescribe it because the five-year results show the disease marker returning to normal and thinking skills holding steady against children who received nothing. Insurers will pay for it for the same reason they already pay for other rare-disease treatments. The patient group is tiny, the disease is well documented and fatal, there is no substitute, and the evidence holds up. A credible drug with no competition does not have to fight for demand. The real challenge is finding patients. This disease is not part of standard newborn screening. Most children go years between first symptoms and a confirmed diagnosis. The National MPS Society and the Cure Sanfilippo Foundation work to close that gap through awareness campaigns, sponsored genetic testing, and patient registries that identify families without a diagnosis. The same organizations help families with deductibles and copay costs once a drug is on the market. Reimbursement does not follow automatically from Orphan Drug designation or any other regulatory status. Payers grant coverage case by case through prior authorization. For a fatal pediatric disease with no alternative and strong clinical evidence, coverage typically follows. The foundations provide a practical infrastructure for both locating patients and supporting access.

What do we understand the least?

The first is sales outside the United States. My model gives Spruce real revenue in Europe, Latin America, and Asia. This largely depends on approvals, pricing, and diagnosis rates that are harder to predict than the U.S. The second is manufacturing. Before the FDA approves the drug, Spruce has to prove it can make it the same way every time at full scale, and getting that right is the practical hurdle right now. The third is how many patients actually exist. This disease is not part of standard newborn screening, and no one knows the true number with confidence. I have chosen to build my forecast from patients who are diagnosed today rather than from a larger theoretical estimate, but how quickly diagnosis improves could push the number either way.

Why will this company be significantly larger in 5 years?

An approval turns a company with no sales into a real rare-disease business. My model has sales peaking at about $254 million a year, and to judge whether that is realistic I lean on Brineura. Brineura is the right yardstick because it is an approved drug, made by BioMarin, for a different rare and fatal brain disease in children. Like Spruce's drug it replaces a missing enzyme, and like Spruce's drug it is infused directly into the brain at specialist centers, which makes it about as close a real-world match as possible.

Brineura's actual peak sales were about $162 million, and my $254 million is roughly 1.6 times that figure. The extra $92 million does not come from charging more per patient. My model prices TA-ERT at about $828,000 a year in the United States, which is at or below Brineura's level. The difference is geography. My forecast adds meaningful European and international revenue that Brineura never fully built. I have held the global patient peak at about 304, below the roughly 330 Brineura reached. The whole forecast rests on a diagnosed pool of about 640 patients rather than Spruce's larger theoretical estimate of 3,100. Slightly fewer patients, a similar price, and a broader geographic reach is how $254 million works. The path from a $52 stock to a much larger company runs through four clear events which are the FDA application late in 2026, approval around the middle of 2027, the sale of that government voucher, and the commercial launch. Each one that lands moves the company toward a size the market is not paying for today.

How do we rate management? In what ways do you believe management and culture impact the success of the business?

The leadership team is more experienced than a company this small would suggest, and its recent decisions have been good ones. The chief executive, Javier Szwarcberg, is a medical doctor who previously ran drug development and portfolio strategy at BioMarin, which happens to be the very company that created this drug and still owns the underlying patents. The man running Spruce knew this asset from the inside long before he bought it, and he also held senior roles at two other rare-disease drugmakers, Ultragenyx and Horizon. The finance chief, Samir Gharib, has been a chief financial officer before and has spent his career in biotech finance. A board member, Dr. Kirk Ways, is currently filling the chief medical officer role.

The team's first chapter was a failure because its original drug did not work and the stock collapsed. The second chapter is the reason to pay attention. Management bought a well-tested, late-stage rare-disease drug out of a bankruptcy for very little money and then guided it into agreement with the FDA on a faster approval path, which is a smart use of limited cash. For a company this small the whole question is execution. Can a lean team get a complicated drug approved and launched without a stumble, and can it raise the money it needs without handing away too much of the company. The investment depends on both of those going right. One question worth addressing directly: the stock traded as high as $240 in late 2025 and has since come back to around $52. The company did not sell stock near that peak. The October 2025 private placement raised $46.6 million at $68 per share, priced around the time of the Breakthrough Therapy designation. The April 2026 public offering raised $69 million at $50 per share. In both cases the proceeds went to the company. There is no evidence of insider selling at the high.

What risks are we knowingly taking? What would make these risks unpalatable?

The first is manufacturing. Spruce pushed its FDA filing from earlier in 2026 to the end of the year in order to meet the agency's demand of proving it can produce the drug consistently, and any slip there delays everything. The second is the fast approval path itself. Approval rests on that spinal-fluid marker rather than on years of patient outcomes. Spruce must run a follow-up study to confirm the benefit. If that study misses, the drug can be pulled from the market. The delivery method carries its own distinct risk. Every dose requires infusion through a surgically implanted port in the skull. In trials running a mean of 4.2 years per patient, no deaths occurred and device-related adverse events were described in company filings as consistent with other therapies using the same route. Device complications and infection are real considerations, and every prescriber will weigh them. The third is dilution, the near-certain need to sell more stock before launch. The fourth is overseas sales, which are harder to forecast than the U.S. The fifth is concentration. This is a one-drug company with no backup if the program stumbles. The sixth is the team's own track record of being wrong before. These risks turn from acceptable to dealbreaking if the FDA rejects the marker, refuses the application, fails the manufacturing review, or if the confirmatory study misses.

<u>Critical Questions:</u>

What questions do we have where if we knew the answer, we would significantly INCREASE or DECREASE our position in the stock?

- Will the FDA accept the spinal-fluid marker as enough evidence the drug works, and approve it on the expected schedule?
- How much new stock will the company have to sell to fund itself, at what price, and how much will that cost the people who already own it?
- Will the sales outside the United States actually show up, or is this really a U.S.-only drug?

Working Thesis:

Articulate our working thesis for:

The Business

Spruce will file its drug with the FDA late in 2026 and, because the agency has already accepted its faster approval path, should win approval around the middle of 2027 as the first and only treatment for this disease. My model gives that outcome a 72 percent chance. From there, Spruce builds a focused rare-disease business that peaks at about $254 million in annual sales, drawn from a diagnosed pool of roughly 640 patients and a peak of about 304 patients actually on treatment. High pricing drives the result, near $828,000 per patient a year in the United States and less abroad, with BioMarin taking about 10 percent of sales plus some extra payments when the drug hits agreed goals. A follow-up study to confirm the benefit runs alongside the launch as a condition of the fast approval. On top of product sales sits the one-time government voucher, which stays available because the program was renewed through September 2029 and which my model values at about $83 million after adjusting for the probabilities.

The Stock

My base case is about $131 a share. That number comes from three parts added together. The drug itself is worth roughly $208 million after adjusting for the chance it fails. The one-time approval voucher adds about $83 million. And the company holds about $91 million in cash. Together that is roughly $381 million, which works out to about $131 across 2.9 million shares. I discount future profits at 11 percent to bring them into today's dollars. This is a probability-weighted number. It already prices in a 28 percent chance the FDA says no.

The market is applying a far harsher discount. Back out the net cash and hold every other assumption constant. At around $52, the stock implies roughly 85 percent odds of rejection. My model puts approval odds at 72 percent. The entire trade lives in that gap.

Here is what each outcome looks like. If the FDA approves, the probability discount dissolves and the base case value is about $170 per share. That is what the three-part sum equals when approval is no longer a question. If the FDA rejects, the drug is worth nothing, the voucher is never issued, and the company is left with its cash. Intrinsic value on rejection is about $31 per share, which is net cash per diluted share in today's dollars. The stock would trade below that for a period as the company continues to spend. The three blended probability-weighted values across my operating scenarios are about $65 in the bear, $131 in the base, and $187 in the bull. Each already nets out the 28 percent rejection case. You are buying a blended outcome worth about two and a half times the price, with a cash-backed floor if the bad case hits.

The obvious objection is dilution, and it does not break the thesis. Spruce has cash to run into at least mid-2027, so it will almost certainly sell new stock before the drug pays for itself. It already has the tools in place to do it, a $300 million shelf registration and a $75 million at-the-market facility with Jefferies, so the only open questions are size, price, and timing. Imagine it raises $100 million at the recent price of $52. That issues about 1.9 million new shares and lifts the count to 4.8 million, while the fresh cash brings total value to about $481 million. The math then lands near $100 a share. That drop from $131 is not the business getting worse. It is simply value moving from current owners to new buyers, because stock was sold below what it is truly worth. Even after that cost, $100 is still roughly double where the stock trades today. There is also a softer path. Selling the approval voucher for around $150 million would cover much of the funding gap with little or no new stock, so the dilution I model is closer to a worst case than a certainty.

The thesis holds in every case but one. The single event that would turn this from a buy into a sell is the FDA rejecting the spinal-fluid marker when it reviews the application. Short of that, the entire debate is just about how good the outcome gets.

What Metrics will we monitor to judge if our working thesis is intact?

- Whether the FDA accepts the spinal-fluid marker and the application moves forward
- The approval decision and whether it lands around the middle of 2027
- The company's cash, plus the size, timing, and price of any new stock sale
- How quickly patients start treatment after launch, measured against the path toward about 304 patients
- Progress on the required follow-up study
- The sale of the one-time government voucher

Exhibit A – Income Statement

INCOME STATEMENT														
Year	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**	**2036**	**2037**	**2038**	**2039**	**2040**
Total Revenue	2,794,500	20,522,808	43,910,692	76,098,325	116,907,536	162,687,198	210,170,067	222,211,471	233,591,463	245,337,770	254,136,543	261,539,889	268,527,349	274,444,545
Competition factor	1	1	1	1	1	1	1	1	1	1	1	0.88	0.7744	0.681472
Adj Revnue	**2,794,500**	**20,522,808**	**43,910,692**	**76,098,325**	**116,907,536**	**162,687,198**	**210,170,067**	**222,211,471**	**233,591,463**	**245,337,770**	**254,136,543**	**230,155,102**	**207,947,579**	**187,026,273**
Royalties (BioMarin)	(279,450)	(2,052,281)	(4,391,069)	(7,609,833)	(11,690,754)	(16,268,720)	(21,017,007)	(22,221,147)	(23,359,146)	(24,533,777)	(25,413,654)	(23,015,510)	(20,794,758)	(18,702,627)
COGS	(503,010)	(3,694,105)	(7,903,925)	(13,697,699)	(21,043,357)	(29,283,696)	(37,830,612)	(39,998,065)	(42,046,463)	(44,160,799)	(45,744,578)	(41,427,918)	(37,430,564)	(33,664,729)
R&D	(20,000,000)	(15,000,000)	(14,000,000)	(13,000,000)	(12,000,000)	(11,000,000)	(10,000,000)	(10,000,000)	(10,000,000)	(10,000,000)	(10,000,000)	(10,000,000)	(10,000,000)	(10,000,000)
SG&A	(20,335,340)	(22,462,737)	(25,269,283)	(29,131,799)	(34,028,904)	(39,522,464)	(45,220,408)	(46,665,377)	(48,030,976)	(49,440,532)	(50,496,385)	(47,618,612)	(44,953,709)	(42,443,153)
Milestones (BioMarin)						(25,000,000)		(25,000,000)						
Operating Profit	**(38,323,300)**	**(22,686,315)**	**(7,653,585)**	**12,658,995**	**38,144,522**	**41,612,319**	**96,102,040**	**78,326,883**	**110,154,878**	**117,202,662**	**122,481,926**	**108,093,061**	**94,768,547**	**82,215,764**

Exhibit B – Valuation Summary (rNPV)

OUTPUT OF MODEL	
Sum PV of FCF (2027-40)	166,355,629
TV (on 2040 risked FCF)	178,924,379
PV of TV	41,509,530
PRV (risked, PV)	82,702,703
rNPV (enterprise)	207,865,159
Net Cash	90,662,000
Equity Value	381,229,862
Shares outstanding	2,915,278
Value per share	**130.77**

Exhibit C – Market-Implied Approval Probability

MARKET IMPLIED APPROVAL PROBABILITY	
Current price (input)	51.87
Net cash per share (intercept)	31.10
Unrisked drug + PRV (total)	403,566,475
Per share slope ($/pt of PoS)	138.43
Implied PoS at current price	**15.00%**
Base value/share check (= 140.70)	130.77