

Biotech Frontiers

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# FINDING WINNERS IN THE DISCARD PILE

Playing Pharmaceutical Moneyball  
\$2 Billion in Hidden Balance Sheet Assets

## Finding Winners in the Discard Pile

### **Playing Pharmaceutical Moneyball \$2 Billion in Hidden Balance Sheet Assets**

Kevin Youkilis did not look like a future Major League Baseball (“MLB”) All Star.

His high-school coach described him as “roly poly”... his college coach called him “pudgy”... and the general manager of a franchise who scouted him in the minors dubbed him a “fat kid.” Apart from his unathletic physique, Youkilis also had a highly unconventional batting stance, an extreme crouch over the plate that looked nothing like the classic stances of successful baseball hitters.

Nonetheless, there was one clue in Youkilis’s early performance on the field that caught a few people’s attention – but only those few who themselves had a strange way of evaluating future baseball talent: Youkilis had an incredible knack for earning walks. This gave him an unusually high on-base percentage, not so much because he was hitting the ball well, but because he was patient enough not to swing at pitches that were outside the strike zone.

If you’ve read Michael Lewis’ classic best-seller *Moneyball*, seen the Hollywood adaptation starring Brad Pitt, or if you’re a die-hard Boston Red Sox fan, you know what happens next.

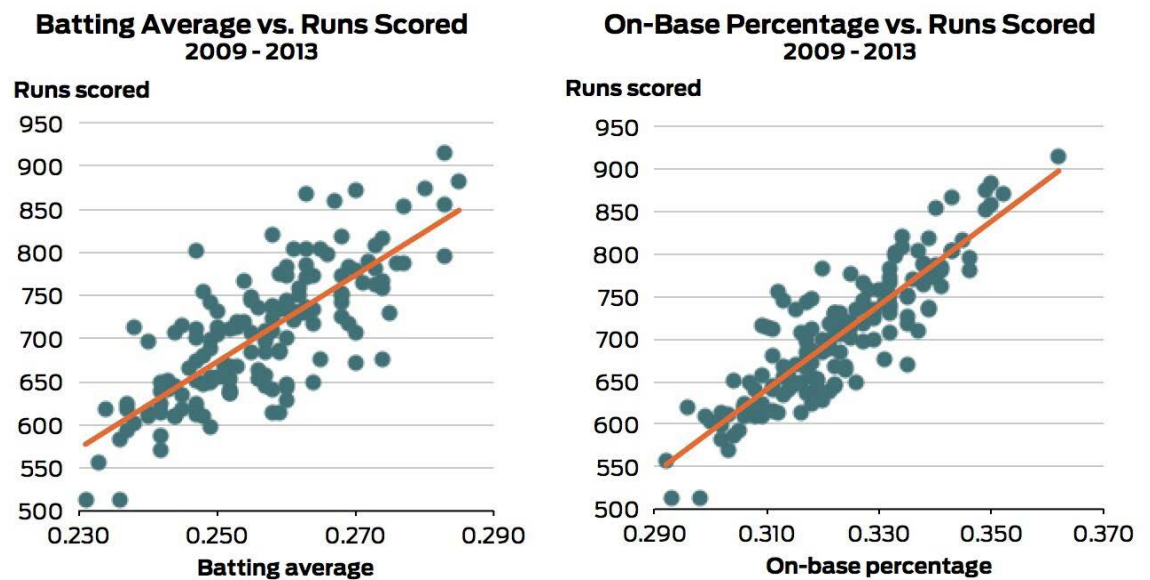
Despite his downright weirdness as a baseball prospect, Kevin Youkilis was selected in the eighth round of the MLB draft by the Red Sox, who swooped in to pick him ahead of the Oakland A’s – my team, who had hoped Youkilis would fall even further down in the draft.

Youkilis would go on to have a storied career with the Red Sox – making three MLB All Star teams, being part of two World Series championships, and winning a Golden Glove fielding award as the team’s first baseman.

But it was Youkilis’s high-profile appearance in Lewis’s *Moneyball* that would make him famous among an entirely new audience – finance, statistics, and investment geeks.

Let me explain...

*Moneyball* describes the disruptive approach that a handful of data-driven analysts used to turn professional baseball upside down. Crunching data and adapting statistical tools that had never been applied to pro sports, these analysts devised a new lens for evaluating baseball talent. This lens enabled them to see prospective players in a totally different way. Factors like a player's physique or batting stance no longer mattered. Nor did the opinions of the crusty pro scouts who had dominated baseball's player assessment for decades. Instead, these brash young analysts cared only about the "sabermetrics," advanced statistics that predicted a player's probable impact on wins and losses.



*Moneyball* is so compelling because at its heart it's a story of David versus Goliath. The book explains how one of baseball's smallest, poorest franchises – the Oakland A's – put together a multi-year-long streak of improbable successes against their rich rivals like the New York Yankees... simply by drafting players that most of the other MLB teams thought didn't have a place in professional baseball and belonged in the discard pile.

In this issue of *Biotech Frontiers*, we're going to focus on an upstart company that's playing "pharmaceutical moneyball" – like the gritty Oakland A's, it looks at the drug-development gameboard through a new lens and uses its novel approach to turn things upside down in its favor. As we'll make clear when we adjust its balance sheet properly, this company also trades at a negative enterprise value, which most of Wall Street hasn't seemed to notice... and which makes the company a compelling value with an exceptional margin of safety.

This month's recommendation is **Roivant Sciences (Nasdaq: ROIV)**. And, as we'll routinely do, we'll apply the seven-part framework we laid out in the [Biotech Frontiers Investment Guidebook](#) to explore why it merits a place in our portfolio.

## I. The Science

In [last month's issue](#), we wrote about a quintessential scientific breakthrough – the discovery of Tumor Infiltrating Lymphocytes (“TIL”) and how to expand them *in vitro* – as well as the scientific giant who made these discoveries, Dr. Steven Rosenberg. As I described in the *Investment Guidebook*, tracking breakthrough science and the scientists behind it will often be at the heart of our hunt for compelling investment opportunities. But sometimes, game-changing innovation can happen not so much in the fundamental science itself, but instead in how one approaches *sifting through the science* to search for promising new medicines. That's the crucial innovation at Roivant.

### The Big Pharma Discard Pile

Big Pharma – the Eli Lillys, Johnson & Johnsons, and Mercks of the world – spends about \$350 billion *per year* on the research and development (R&D) of new medicines. This enormous financial investment churns a flywheel that puts roughly 15,000 novel therapies into Big Pharma's research pipeline at any given time. Yet in 2023, the U.S. Food and Drug Administration (“FDA”) approved only 55 new drugs... in 2022, only 37... in 2021, only 50.

So there is a staggering mismatch between the number of novel therapies under development, and those actually approved for use in the clinic. What happens with all the unapproved compounds in Big Pharma's pipeline? The answer is: Many of them are, literally and figuratively, sitting on the shelf. Conducting clinical trials and pursuing regulatory approvals are expensive, with costs often running into the hundreds of millions of dollars per drug. As a result, even well-resourced Big Pharma companies can only focus on advancing a small number of candidate drugs for FDA approval.

Imagine a giant chessboard, with thousands of rows instead of the standard eight. Each compound in Big Pharma's pipeline is a pawn. Big Pharma focuses intensively on the few pawns that are getting close to the far side of the game board, knowing that if they make it all the way across, they'll become queens. The rest of the pawns? Most of them sit there doing nothing.

Indeed, like the MLB player scouts, Big Pharma has its own discard pile. The discard pile consists of compounds that Big Pharma companies have explicitly given up on – say, because of a shift in strategic priorities (e.g., a turn away from a specific disease area), or because a key scientific sponsor at the company leaves, or because the early data about a compound isn't as convincing as the company had hoped. Once a compound gets placed in Big Pharma's discard pile, it's available for purchase... often at a fire-sale price. Think of these as the pawns Big Pharma has decided to sacrifice.

*Biotech Frontiers* subscribers are already familiar with a compound that made a spectacular comeback from the discard pile. Ibrutinib – the first Bruton's tyrosine kinase ("BTK") inhibitor, which became a transformative therapy for deadly B-cell cancers and drove Big Pharma giant AbbVie's \$21 billion acquisition of Pharmacyclics – began its life as a compound called CRA 032765. It originated at Celera (hence the abbreviation CRA), the once high-flying biotech company helmed by human-genome-mapping pioneer Craig Venter. When Celera fell on hard times and had to liquidate most of its portfolio, Pharmacyclics' founding CEO, Dr. Richard Miller, swooped in and bought CRA 032765, along with two other drug candidates in Celera's discard pile, for a measly \$6.6 million. The rest is history.

My favorite Big Pharma discard-pile story, though, concerns a compound that escaped being tossed onto the pile by the slimmest of margins. Merck's PD-1 inhibitor Keytruda, approved to treat 17 different tumor types, is currently the best-selling drug in the world. In 2023, Keytruda generated \$25 billion in revenue – nearly half of Merck's total sales of \$60 billion. To put this into context, Merck's second most valuable drug, the HPV vaccine Gardasil, generated \$9 billion in 2023, about a third as much as Keytruda did. It's not much of an exaggeration to say that Keytruda *is* Merck.

What most people don't know is that Merck did not invent Keytruda. The compound that became Keytruda was invented at a Dutch company called Organon, which was bought by Schering-Plough, which Merck in turn acquired mainly for its nasal spray Nasonex. What's more, the Organon PD-1 that became Keytruda was put into Merck's discard pile and reached a point where Merck had actually negotiated a term sheet to sell the drug for peanuts. Someone at Merck stepped in to cancel that deal before it closed – but it's bracing to realize that Merck came close to giving away Keytruda for next to nothing.

## Sifting the Discard Pile for Value

With this context in mind, let's circle back to Roivant Sciences.

After several years managing the biotech portfolio at hedge fund QVT with great success, Vivek Ramaswamy asked a series of potent questions: What if there were a biotech company focused on identifying the unrecognized gems in Big Pharma's discard pile? Moreover, what if that biotech company approached the task of identifying these unrecognized gems in a highly data-driven way, similar to the rigorous methods QVT applied to picking biotech stocks?

For example, what if that biotech company invested in building a massive database of *all* the drugs in Big Pharma's pipeline, and could analyze each one across several dimensions – such as the drug's competitive landscape, potential market size, and probability of success? Finally, what if this new biotech company then used its database, and its proprietary analysis, to cherry pick the most promising compounds in Big Pharma's discard pile – and especially the ones that it could buy at dirt-cheap prices?

Ramaswamy's thought experiment became Roivant's business plan.

But it's one thing to come up with a clever, potentially disruptive business plan... and quite another to execute it. So how has Roivant done on the execution?

We'll get to some aggregate metrics on Roivant's performance in a bit. I want to start with a story about Roivant that tells us all we really need to know about the company's ability to execute.

### 100x in 10 Months

Inflammatory Bowel Disease (“IBD”), a category that includes Crohn's disease and ulcerative colitis, describes a group of gastrointestinal (“GI”) disorders that afflict 8 million people globally. People with IBD suffer from chronic inflammation of their GI tracts that often have a devastating impact on quality of life and life expectancy. Unfortunately, existing medicines for IBD have limited effectiveness – only about 20% of patients treated with approved therapies experience remission.

In 2021, Roivant identified a compound in Big Pharma giant Pfizer's discard pile dubbed PF-0648065. This compound belonged to a promising new class of monoclonal antibodies called TL1A cytokine inhibitors, which work to modulate the body's inflammatory response. Despite this promise, the compound was stuck on the shelf at Pfizer. The Big Pharma giant chose instead to prioritize a different therapy for IBD in its pipeline called etrasimod, which was closer to regulatory approval. Etrasimod was the pawn further across the gameboard and therefore attracted Pfizer's resources. PF-0648065 languished.



Roivant struck a deal with Pfizer to license PF-0648065 through a joint venture (“JV”). Under the terms of the deal, Roivant and Pfizer would form a new company called Televant, which would be a Roivant subsidiary. Televant would own the rights to develop and commercialize PF-0648065, which would be renamed RVT-3101. Roivant would own 75% of Televant, Pfizer 25%. For its 75% stake, Roivant would pay Pfizer \$45 million – not as low as the \$6.6 million that Richard Miller paid Celera for the drug that became ibrutinib, but as we’ll see, still a bargain.

Roivant would invest an additional \$5 million in RVT-3101 to fund the completion of an important Phase IIb clinical trial on this compound, called the TUSCANY-2 study. Just seven months after Roivant struck the deal with Pfizer, the TUSCANY-2 trial topline results became available, and they were jaw-dropping: RVT-3101 induced a 36% remission rate in patients with ulcerative colitis, with 50% of patients showing endoscopic improvement. RVT-3101’s efficacy in the trial was nearly two times better than the existing standard of care. To top it off, the trial suggested that RVT-3101 has an immaculate safety and side-effect profile.

In October 2023, a mere 10 months after Roivant inked the deal with Pfizer that for \$45 million gave it 75% ownership of RVT-3101, Big Pharma player Roche bought Televant for \$7.1 billion. Roivant’s three-quarters share of the payout was \$5.3 billion – **a greater than 100x return on investment in less than a year.**

When he founded Roivant, Vivek Ramaswamy explained that the “Roi” in the company’s name stands for “return on investment.” Roivant’s coup with RVT-3101 proves that the name choice was no gimmick.

## A Track Record of Success

Skeptics dismiss the Televant story as a lucky break... but Roivant's track record picking winners out of Big Pharma's discard pile suggests otherwise. Since its founding, Roivant's distinctive approach to buying Big Pharma's rejects has yielded six FDA-approved drugs and 10 consecutive positive Phase 3 clinical trials for compounds that Roivant in-licensed. The company's R&D spending productivity – at roughly \$85 million spent per Phase 2 or Phase 3 clinical-trial readout – makes it between 5x and 10x more efficient than its Big Pharma peers. (A readout is when trial results are made public.)

Roivant's pipeline features several compounds that could prove to be as valuable as RVT-3101. Moreover, as we'll discuss later, Roivant's balance sheet now gives it the financial wherewithal to significantly accelerate the innovative process it's already demonstrated can deliver blockbuster wins. All this suggests we've only begun to see the success Roivant can achieve on the infinitely large pharmaceutical chessboard with its own distinctive strategy.

## II. Sizing the Prize: The Opportunity

"If you're right, you've *got* to get paid." *Biotech Frontiers* subscribers are likely to hear me repeat on a monthly basis my old mentor Julian Robertson's mantra... It's a useful reminder that we aim for the investments we explore to pay us a multiple of our money if they work.

We can then turn Julian's mantra into a question: *How* are we going to get paid? To answer this question, we size the market our company is pursuing and make some reasonable assumptions about its probability of success. That arithmetic gives us an expected value ("EV"). In the last step, we compare the company's current market capitalization to its EV.

### Valuing Roivant's Pipeline

Roivant Sciences currently has at least three drugs in its pipeline that have blockbuster potential – i.e., the potential to generate at least \$1 billion in sales.

The first is Vtama, a topical cream used to treat inflammatory skin conditions such as plaque psoriasis, atopic dermatitis, and others. Vtama is a first-in-class therapy that belongs to a novel category called aryl hydrocarbon receptor agonists. The most important practical differentiator of drugs in this category is that they aren't steroids... and therefore have none of the unpleasant, dangerous long-term side effects that steroids have.



While Vtama has so far been approved by the FDA only to treat plaque psoriasis, the emerging clinical trial data on its efficacy for other inflammatory skin conditions such as atopic dermatitis is striking. This data gives Roivant well-justified confidence that Vtama will eventually win approval for a much broader class of skin disorders. And the ultimate addressable market for the drug is huge: 137 million patients in the U.S. alone.

Vtama is already on track to generate \$100 million in annual revenue for Roivant. But it's reasonable to imagine that five to seven years from now, these sales will grow 10x to 50x. Vtama could eventually be a \$1 billion to \$5 billion drug. Vtama has already proven itself from a scientific, regulatory, and commercial standpoint. What's left is execution... and as we've already established, Roivant knows how to execute.

A reliable rule of thumb is that a blockbuster drug's value is at least 3x its peak sales. Let's take \$2.5 billion, the midpoint of the \$1 billion to \$5 billion range, as a reasonable estimate of Vtama's peak. That implies about \$7.5 billion of value for Roivant.

Roivant's two other potential blockbusters both target autoimmune diseases, which occur when the immune system attacks the body itself. These are some of the most awful diseases we know of – virtually always devastating to a patient's quality of life, and in many cases life threatening.

Roivant's more-advanced autoimmune-disease candidate, Batoclimab, is already in Phase III clinical trials for Myasthenia Gravis and for thyroid eye disease, and in Phase II trials for Graves disease and for CIDP. Roivant's second drug candidate in the autoimmune category, RVT-1402, is at a much earlier stage – still in Phase I trials. But the data on RVT-1402 suggests that it may be a best-in-class molecule – in effect, a more effective version of Batoclimab, with an equally benign safety profile.

Roivant believes that, across the full range of autoimmune diseases that these drugs can treat, Batoclimab and RVT-1402 together can eventually generate at least \$10 billion in annual revenue. I've studied the available data on these compounds as well as the indications they target, and I don't think Roivant's estimate is off the mark. But I'm inclined to reduce the probability of success to 50%. Three times \$5 billion in probability-adjusted peak sales is \$15 billion of value. But here we need to make one further adjustment: While Roivant owns 100% of Vtama, it only owns about 55% of Batoclimab and RVT-1402 through its subsidiary Immunovant (IMVT). That 55% ownership implies \$8.25 billion in value to Roivant from these two autoimmune drug candidates.

We can now estimate the expected value (“EV”) of Roivant’s three most identifiable potential blockbusters:



### Roivant Potential Blockbusters

Drug	Disease Targets	Stage Phase	Estimated Peak Sales	Probability Factor	Roivant Ownership	EV to Roivant
Vtama	Inflammatory Skin Diseases	Commercial and Phase III	\$2.5 Billion	100%	100%	\$7.5 Billion
Batoclimab and RVT-1402	Autoimmune Diseases	Phase III and Phase II Phase I	\$10 Billion	50%	55%	\$8.25 Billion
					<b>Total EV:</b>	<b>\$15.75 Billion</b>

Roivant’s current market capitalization is \$9.3 billion. The company has \$7 billion of net cash... and a hidden asset on its balance sheet that is conservatively worth another \$2 billion to \$5 billion. Let’s leave that hidden asset for the moment. It’s still appropriate to back out Roivant’s net cash from its market cap to zero in on how the market is valuing Roivant’s business. Take \$9.3 billion less \$7 billion of net cash to get \$2.3 billion of cash-adjusted market cap – versus our EV estimate of \$15.75 billion. That implies a 6x to 7x return... more than enough to satisfy Julian’s instruction to “get paid.”

### Roivant’s Alpha

There’s another way to think about Roivant’s value.

On Wall Street, the term “alpha” refers to the return from active stock picking versus the overall market. Positive alpha is the increment over and above the market’s return that a money manager creates by picking winners. Negative alpha describes the value destruction relative to the market that results from poor stock picking.

Alpha is a useful way to quantify a money manager's skill. The best-known example of this is probably Warren Buffett at Berkshire Hathaway. Every Berkshire annual report provides the average annualized return of Berkshire stock and compares it to the S&P 500 since Buffett assumed control in 1965. This year, the comparison appears [on page 17 of Berkshire's annual report](#), and shows Berkshire's average annual gain from 1965 to 2023 to be 19.8% versus the S&P's 10.2%. Nearly doubling the S&P's performance over a 60-year span is a staggering achievement – one that offers a quantitative anchor for Buffett's reputation as an investor.

It's revealing to perform a similar calculation for Roivant. The number is likely to fall short of being perfectly precise because we lack the data we would need for such precision. But I think it's directionally correct.

Roivant was formed in 2014 with about \$100 million in seed capital. The company's market capitalization today is \$9.3 billion – or 93x its initial value. Appreciating 93x over a decade translates into a 57.3% annualized return. Over the same period, the S&P 500 has returned 12.5% annualized, and the S&P 500's flagship biotech ETF (XBI) 8.5%.

Let's pause for a moment to appreciate these figures: Over its 10-year life, Roivant has outperformed the overall S&P 500 by an average of 4.5x and the large-cap biotech sector by 6.7x *annually*. I am going to make an educated guess that these figures match Buffett's during the very best investing decade of his storied 70-year career.

What can they tell us about Roivant's future value? Although I have a lot of respect for what Roivant has achieved to date, I don't believe that earning 57% returns annually is sustainable over the long term. For starters, Roivant now has a lot more capital to deploy, and as Buffett has rightly observed, deploying larger sums of capital is harder. So let's assume that over the second decade of its life, Roivant's annual returns get cut by more than half, from 57% to 25%.

Compounding its value at 25% per year, Roivant would double in slightly more than three years and triple in about five... more than fast enough to satisfy Julian's exhortation to "get paid."

### III. The Capitalization Table

In the case of [last month's lovance Biotherapeutics \(Nasdaq: IOVA\) recommendation](#), the Cap Table played an important role in our investment thesis. Wayne Rothbaum may be the best biotech investor in the world, and he is both lovance's largest shareholder as well as a director. The history of Rothbaum's lovance stock purchases also carried meaningful information – for example, we could infer from his significant buys over the past 24 months that he believed lovance stock presented a compelling bargain. Since the stock had not rallied materially from the level of his buys, that bargain remained available to us.

Roivant's Cap Table is not as significant a driver of our recommendation, but it does contain some valuable clues that support owning the stock. The company's largest shareholder, at nearly 14%, is QVT Financial. Originally a large, multi-strategy hedge fund, QVT converted into QVT Financial, a family office, in 2018 and mainly manages the wealth of its own principals – with the biggest piece belonging to CEO Dan Gold, a Harvard-trained physics major who pursued a successful career on Wall Street. I like QVT's family-office conversion, because it means the firm is now betting largely with its own skin in the game, not with other people's money. Furthermore, while it's hard to get precise data, QVT's total assets under management appear to be around \$4 billion. Its Roivant position is about \$1.27 billion, making it a huge, concentrated investment for QVT that is by far the firm's largest, at about 30% of assets. That is a positive signal that speaks powerfully to QVT's level of conviction about Roivant's value.

There's also the history between Roivant and QVT. Vivek Ramaswamy worked at QVT from 2007 to 2014, making partner there in just three years and managing QVT's biotech portfolio. He left QVT to found Roivant, and when he did, QVT as a firm as well as its principals were among his earliest financial backers. But what's notable to me is the length of time QVT has been invested in Roivant – 10 years and counting – and that QVT has grown its position over time.

QVT knew about Roivant when it was still an unfunded business plan. Sticking around for a decade and growing the investment over that period suggests to me that QVT sees Roivant executing on its promise. When he founded Roivant, Ramaswamy spoke about aspiring to build a “biotech Berkshire Hathaway.” Berkshire, of course, is famous for winning over shareholders that stay for life. It's an auspicious sign that Roivant's largest shareholder has been a shareholder from the very start... and has all the history at its disposal to assess whether Roivant is doing what it set out to do.

What about Ramaswamy himself? He still owns 6.4% of Roivant, making him the company's sixth-largest shareholder. Ramaswamy has been selling down his stake, most recently in January when he sold 3 million shares to leave him with 52 million. His remaining Roivant investment is worth well over \$500 million, making it a meaningful part of his net worth. Ordinarily, we don't like to see founders and former CEOs selling – it's usually a bearish sign. But given Ramaswamy's transition from Wall Street to politics (he ran unsuccessfully in this year's Republican primaries aiming to be the party's presidential candidate), his sales make sense, and I don't read them as a negative signal.

I care more about two other key people at Roivant – CEO Matt Gline and President and Chief Investment Officer Mayukh Sukhatme, who like Gline sits on Roivant's board. Together, these two have been responsible for virtually all of the major decisions at Roivant since Ramaswamy left in 2021. They were arguably more important decision makers than Ramaswamy himself in the years prior.



Both have impressive pedigrees: Gline (pictured left) is a Harvard-trained physicist who joined Roivant at its founding, served as the company's chief financial officer, and was promoted to CEO as Ramaswamy's successor. Sukhatme (pictured right) earned his undergraduate degree at MIT before earning an MD from Harvard Medical School. He joined Roivant a year after its founding and has been the company's chief dealmaker ever since. Sukhatme, more than anyone, deserves credit for the astonishing transactions in which Roivant acquired from Pfizer for \$45 million a compound that became RV-3101 and sold it to Roche less than a year later for \$7.1 billion. Happily for us, both Gline and Sukhatme own a meaningful amount of Roivant stock: Gline 1 million shares, Sukhatme 4 million – and these figures do not include their options packages, which would take their shareholdings up materially. It's a terrific sign that Roivant's two most important people, like its largest investor QVT, have a lot of skin in the game.

#### IV. The Balance Sheet

In the [first issue of Biotech Frontiers](#), we did a “deep dive” into negative-enterprise-value opportunities in the biotech sector... and recommended buying a basket of negative-enterprise-value biotech stocks. Most of the stocks in that basket are relatively small – only one, **Vir Biotechnology (Nasdaq: VIR)**, features a market capitalization above \$1 billion. This trend makes sense: We would not expect the larger, well-known biotech players to trade at a negative enterprise value. And with only a few exceptions, they don't.

I was genuinely surprised to learn that Roivant is a negative-enterprise-value stock, once we understand its balance sheet properly. Let me explain...

Roivant has three significant assets on its balance sheet.

The first is the simplest: \$7 billion of cash, with no offsetting debt on the liabilities side. The second is Roivant's 55% stake in its publicly traded subsidiary Immunovant (IMVT), the company that holds the two previously mentioned potential autoimmune blockbusters Batoclimab and RVT-1402. Immunovant's market capitalization is \$5.5 billion, making Roivant's stake worth \$3 billion.

Together, Roivant's cash (\$7 billion) and its stake in Immunovant (\$3 billion) exceed Roivant's market capitalization (\$9.3 billion) by nearly \$700 million. To put it differently, these two assets by themselves give Roivant a negative enterprise value of \$700 million.

But Roivant also has a third important asset that few observers are paying attention to: Its patent-infringement lawsuits against Moderna and Pfizer, asserting that these Big Pharma giants infringed on key Roivant patents in developing their COVID-19 vaccines.

In the argot of Wall Street, these lawsuits comprise a "litigation asset." We call them litigation assets because their value depends on the outcome of litigation: If Roivant wins its lawsuits or settles them favorably, it could reap billions and even tens of billions of dollars. If it loses, the litigation could be worth nothing. The value of litigation assets is always probabilistic, meaning that it requires us to make some educated guesses about the probable outcomes to assess the asset's expected value.

As an aside, I love litigation assets embedded within investment opportunities. Why? Because most investors, and especially mainstream Wall Street institutions, are terrible at analyzing them. To form a view on a litigation asset's value, we must carefully wade through hundreds (sometimes thousands) of pages of legal filings and make nuanced judgments about esoteric questions of law. This is simply not an exercise most investors have either the appetite or capabilities to do. But *their* blind spot... creates *our* opportunity.

To help us get a handle on Roivant's litigation asset, I reached out to Mr. X, who would only agree to assist us if I could ensure his anonymity.

Mr. X and I attended Yale Law School together a little over 25 years ago. Since that time, Mr. X has established himself as one of the foremost intellectual property ("IP") lawyers in the world. He currently teaches IP law at one of America's top law schools. On the side, he is frequently asked to consult on the highest-stakes IP litigation happening. For example, when Microsoft finds itself engaged in patent litigation with billions of dollars at stake... Mr. X gets a call. We've been friends since our days in school and have worked together several times over the years. I've observed that when it comes to high-stakes IP litigation, Mr. X is rarely wrong.

I also want to be clear – I didn't ask for Mr. X's help by calling in a favor. His time is extraordinarily valuable, and Roivant's lawsuits against Moderna and Pfizer are exceptionally complex. So he and I came up with a budget that would enable him to get a reasonable handle on the cases. And I talked Porter & Co. into paying his bill.

So what did we learn from Mr. X?

Let's start with a brief description of what these cases are about. As most people know, Moderna's and Pfizer's COVID-19 vaccines are part of a novel, emerging therapeutic category called mRNA vaccines. mRNA, which stands for messenger RNA, is the chemical relative of DNA that directs cells to make specific proteins. Arguably the hardest technological challenge in developing mRNA medicines is engineering a safe, effective way to deliver the mRNA into human cells.

In 2018, Roivant and a partner named Arbutus formed a JV, Genevant, with Roivant owning 51% of the JV. Genevant in turn developed and refined a technology called Lipid Nanoparticles ("LNP") that has become the most effective mRNA delivery system. LNP technology surrounds mRNA with microscopic globules built from four carefully selected types of fat-like molecules. These globules shelter the mRNA and enable it to travel safely through the human body until it reaches a target cell's membrane. The LNPs then cross the cell membrane and release the mRNA. Without LNPs – which Arbutus and Genevant played a significant role in perfecting – mRNA would quickly degrade in the body and be ineffective.

Genevant's and Arbutus' lawsuits against Moderna and Pfizer – from which Roivant stands to benefit as Genevant's 51% owner – assert that the two Big Pharma giants' COVID-19 vaccines infringed upon key patents protecting innovation in LNP technology, without which these vaccines could never have delivered mRNA into the body successfully.

The details of Roivant's lawsuits against Moderna and Pfizer could easily take up an entire issue of *Biotech Frontiers*. They are fascinating and provide a kaleidoscopic look into the importance of IP law in the development of novel medicines. Perhaps we'll revisit them in detail in a future issue.

For now, let me distill the most important things we need to know:

- Moderna's and Pfizer's first line of defense against Roivant was to attack the patents and try to have them declared invalid. In IP law, the validity of underlying patents is a crucial threshold issue. If the patents are invalid, the lawsuit is dismissed. But crucially for Roivant, the court upheld the validity of its patents. This ruling was an important victory.
- In 2021 and 2022 alone, the Moderna and Pfizer COVID-19 vaccines generated over \$110 billion in sales. If a plaintiff prevails in a patent-infringement lawsuit, the damages that result are usually granted in the form of a "reasonable royalty" on past sales. If Roivant ultimately prevails here, even a small royalty would translate into billions because of the size of those sales.
- At least 90% of high-stakes IP lawsuits that involve valid patents settle. That makes sense because a settlement reduces risk for both sides. If the trend holds true here, the key questions then become when will a settlement happen, and at what amount? Mr. X believes that a settlement in these lawsuits is probably at least a year away... and that interim rulings in the coming year will have a major impact on the likely settlement amount.

In a famous scene in Quentin Tarantino’s classic film *Pulp Fiction*, Winston Wolfe (played by Harvey Keitel) tells Jimmie (played by Tarantino himself): “I’m an Oak man myself, Jimmie... I like Oak. How about you?”

If I were Wolfe, my line would be: “I’m a numbers man myself, Jimmie... I like numbers.” And so I asked Mr. X to help come up with an expected-value analysis on Roivant’s lawsuits based on what information we have available now. Bear in mind, these numbers aren’t meant to be a precise prediction. Instead, their purpose is to help us understand, at an order of magnitude, the potential outcomes for Roivant.

In the Upside Case, for example, we figure a \$670 million contribution by taking Roivant’s 51% of the \$6.6 billion in potential royalties and multiplying that by the 20% probability of this outcome ( $.2 \times \$6.6 \times .51 = \$0.67$  billion). Here is our EV:



### How the Patent Fight Plays Out

Scenario	Description	Probability	Royalty Granted	Total Sales (\$billions)	Royalty (\$billions)	Roivant's Share	EV Contribution
Downside Case	No settlement and Roivant gets nothing	20%	0%	\$110	\$0	51%	
Base Case	Settlement with 3% royalty	50%	3%	\$110	\$3.3	51%	\$0.84
Upside Case	Settlement with 6% royalty	20%	6%	\$110	\$6.6	51%	\$0.67
Blue Sky Win	No settlement, Roivant wins and gets a 10% royalty	10%	10%	\$110	\$11	51%	\$0.56
Expected Value (\$billions):							\$2.1

With an expected value of \$2.1 billion for Roivant’s litigation asset, the total balance sheet suggests the company currently trades with a compelling negative enterprise value of \$2.8 billion.

## V. The Catalysts

*Biotech Frontiers* subscribers are already familiar with the importance of catalysts in unlocking value. First, liver-disease company **Sagimet Biosciences (Nasdaq: SGMT)** – part of our initial 10-stock negative-enterprise-value portfolio – delivered Phase IIb clinical-trial results that caused the stock to appreciate more than 200%... before the company’s own capital raise, followed by Eli Lilly’s announcement of results for its competitor drug, caused Sagimet’s stock to fall back near its previous level. Then, lovance received accelerated approval from the



FDA for its path-breaking TIL therapy for advanced melanoma, causing the stock to appreciate 100%.

Over 2024 and 2025, Roivant offers us a rich slate of catalysts that fall into three key categories:

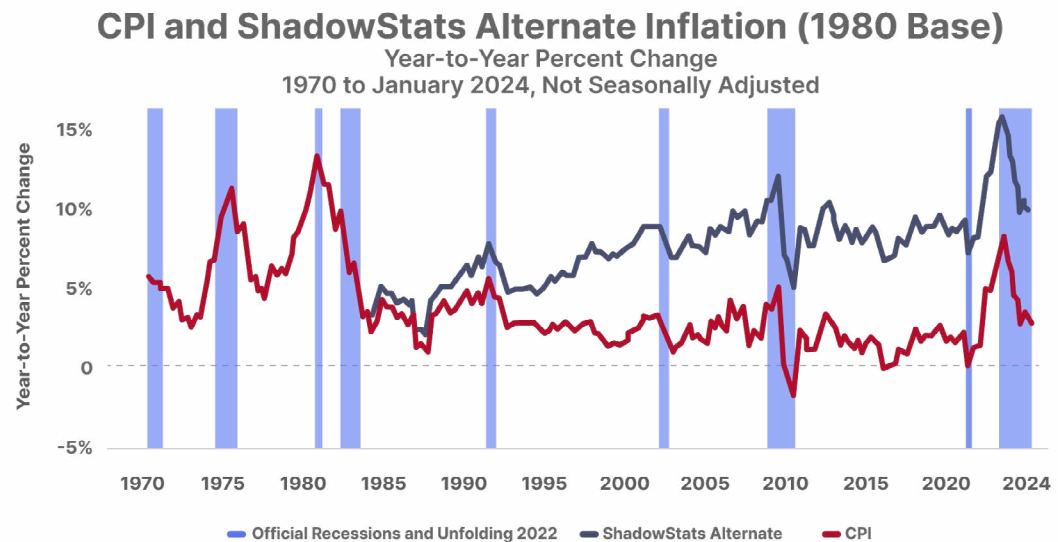
1. *Potential drug approvals and clinical-trial readouts:* In 2024, Roivant will seek approval from the FDA for its Vtama topical skin cream to treat atopic dermatitis, with an FDA decision anticipated in the second half of the year. Approval would significantly expand the patient population that Vtama can reach. In 2024 and 2025, Roivant will have at least five major Phase II or Phase III clinical-trial readouts for promising drugs in its pipeline, including heavily anticipated Phase III results for its potential autoimmune blockbuster Batoclimab.
2. *Balance sheet cash and Immunovant stake:* As we've seen, Roivant's balance sheet features \$7 billion of net cash as well as a 55% stake in subsidiary Immunovant, worth \$3 billion. Over 2024 and 2025, Roivant will make some important decisions about what to do with these assets. It could decide to return some of this cash to shareholders by buying back stock or declaring a special dividend. Or it could deploy some of this cash to purchase new assets, such as the RVT-3101 asset that returned 100x in 10 months. Roivant's CEO has also stated that the company has received multiple overtures to buy Immunovant. A sale, if it happened, would only be likely at a significant premium to Immunovant's current stock price and would give Roivant an even larger cash pile with which to grow shareholder value.
3. *LNP litigation asset:* 2024 and 2025 will also likely see meaningful progress in Roivant's patent lawsuits against Moderna and Pfizer. While it's unlikely these cases would be tried to a final judgment much less to the point of final appeals, they could conceivably settle... or Roivant could benefit from favorable rulings that increase the lawsuits' EV.

Each of these categories gives us reason to believe we won't need to rely on hope to drive appreciation in Roivant's share price over the coming years.

## VI. The Big-Picture Backdrop

The January consumer price index (CPI) report, released on February 13, showed that inflation rose to 3.1% annualized – higher than consensus had expected, and a slight month-over-month acceleration from December (0.3% month-on-month increase versus 0.2% the month before). Wall Street promptly rolled back the probability of the Federal Reserve announcing rate cuts at its March meeting and reduced its expectations of the central bank's total rate cuts in 2024 to a figure approaching 75 basis points versus previous expectations of 150 basis points.

The deeper problem, I believe, is that actual inflation in the U.S. is running a lot higher than the CPI data reflects. I subscribe to economist John Williams' excellent [Shadow Statistics service](#), which aims to adjust the government's economic data so that it more accurately captures what ordinary Americans experience in their lives. The chart below compares the government's CPI data (in red) with Shadow Statistics' adjusted inflation metric (in blue):



Source: ShadowStats, BLS

As the chart suggests, the government may claim that inflation is running at about 3% annualized. But many Americans are experiencing inflation closer to 10% to 12% annualized, one reason the polling data indicates they're so dissatisfied with the Biden administration's economic track record.

Fed Chair Jerome Powell may be many things but I don't think he's a dummy. In particular, I don't think Powell wishes to be remembered in the same breath as the infamous Arthur Burns, the Fed chair who ushered in years of economic calamity in the 1970s by cutting rates before inflation was truly gone. For these reasons, I suspect the Fed is going to exhibit caution before cutting rates this year... And that by the time the year is done, the market is more likely than not to be disappointed by the total amount of rate cuts.

If I'm right, the biotech market will likely experience a pullback. (For those who don't immediately get why, please revisit our detailed discussion of the relationship between interest rates and biotech stocks in section VI of our [Biotech Frontiers Investment Guidebook](#).) I would welcome that pullback, because it would give us a terrific opportunity to load up on our favorite biotech opportunities. However, this outlook also means we will make a point to book profit on some of our biggest winners, so that we don't experience regret if we watch these names soar and then fall back amid an interest-rate-driven short-term retreat.

## VII. Expected Value and Risk/Reward

In the final piece of our analysis, we synthesize everything that's come before and distill it into three capsules: a Premortem statement, a Parade statement, and an Expected Value tree for the proposed investment.

In our **Premortem**, we engage in the following thought experiment: Imagine it's three to five years from now and our investment has not worked out. Why did it fail? By answering this question, we force ourselves to reckon with what could go wrong.

Here is our Premortem for Roivant Sciences: The company's streak of 10 consecutive positive Phase III clinical trials is broken. Instead, Roivant experiences bad luck, and the next several Phase II and Phase III clinical-trial readouts are disappointing. Out of keeping with its history to date, the company's capital allocation also veers into disappointment – for example, Roivant invests in a few compounds that quickly prove to be a bust, leaving the impression that the company has lost its touch or become careless with its capital. Finally, Roivant suffers setbacks in its patent lawsuits, perhaps even receiving an interim ruling that appears to foreclose a successful settlement.

A **Parade** statement is the mirror image of a Premortem: We invite ourselves to imagine it's three to five years from now and our investment has been a spectacular success. What went right? Here, too, we are seeking to clarify the likely drivers of our upside so we can reflect on them alongside what could go wrong.

Our Parade statement for Roivant goes something like this: The company's winning streak in its Phase II and Phase III clinical trials continues, and the market begins to give more credit to Roivant's own prediction that its autoimmune franchise alone is capable of generating \$10 billion in annual revenues after 2026. In the meantime, the superb capital allocation Roivant has demonstrated so far continues, yielding visible results. For example, the company invests in another compound such as IBD treatment RVT-3101 that it flips back to Big Pharma for another striking return. Finally, Roivant reaps a series of positive rulings in its patent lawsuits, perhaps compelling Moderna to push for a settlement at a multibillion-dollar number.

Our **Expected Value Tree** distills everything that's come before into simple arithmetic. We begin by encapsulating our entire investment thesis into a downside scenario, a base-case scenario, and an upside scenario. We assign a probability and a stock price to each. And we derive our EV for the stock based on the sum of these three probability-weighted scenarios and their respective contributions. Here is my Expected Value Tree for Roivant:



## EV Tree for Roivant Sciences

Scenario	Summary	Probability	Stock Price	EV Contribution (per share)
Downside Case	Setbacks in clinical trials, capital allocation, lawsuits	20%	\$8	\$1.60
Base Case	Continued strong execution	60%	\$24	\$14.40
Upside Case	Continued strong execution and some good luck	20%	\$36	\$7.20
			Expected Value (per share)	\$23.20

**Action to Take: Buy Roivant Sciences (Nasdaq: ROIV) up to \$13 per share.**

## Portfolio Review

### BIOTECH FRONTIERS | PORTFOLIO

Company Name	Ticker	Purchase Date	Cost Basis	Closing Price	Market Cap (\$m)	Cash (\$m)	Debt (\$m)	Enterprise Value (\$m)	Total Return	Status
VIR BIOTECHNOLOGY	VIR	01-09-2024	\$10.18	\$11.24	\$1,532	\$242	\$125	\$1,415	10.41%	Buy Under \$11.00
LYELL IMMUNOPHARMA	LYEL	01-09-2024	\$2.07	\$3.07	\$802	\$124	\$68	\$746	48.31%	Buy Under \$2.35
NUVATION BIO	NUVB	01-09-2024	\$1.51	\$2.23	\$504	\$24	\$4	\$484	47.68%	Buy Under \$1.80
UNIQUIRE	QUIRE	01-09-2024	\$6.62	\$5.59	\$271	\$241	\$169	\$199	-15.56%	Buy Under \$7.25
SUTRO BIOPHARMA	STRO	01-09-2024	\$4.03	\$4.95	\$302	\$82	\$50	\$271	22.83%	Buy Under \$4.10
ATEA PHARMA	AVIR	01-09-2024	\$3.45	\$4.45	\$375	\$144	\$3	\$235	28.99%	Buy Under \$3.50
KODIAK SCIENCES	KOD	01-09-2024	\$3.16	\$6.01	\$315	\$346	\$88	\$57	90.19%	Buy Under \$3.30
SAGIMET BIO*	SGMT	01-09-2024	\$5.56	\$6.02	\$198	\$207	\$0	\$104	8.27%	Buy Under \$6.75
ATHIRA PHARMA	ATHA	01-09-2024	\$2.87	\$3.94	\$153	\$91	\$2	\$64	37.28%	Buy Under \$3.50
IOVANCE BIOTHERAPEUTICS	IOVA	02-05-2024	\$7.92	\$16.79	\$4,762	\$485	\$85	\$4,363	111.99%	Buy Under \$9.25
CHIMERIX	CMRX	02-08-2024	\$0.91	\$1.17	\$108	\$28	\$2	\$83	28.57%	Buy Under \$1.05
ROIVANT SCIENCES	ROIV	02-29-2024	\$11.37	\$11.37	\$9,300	\$7,000	\$0	-\$2,800	0.00%	Buy Under \$13.00

Closed Positions	Purchase Date	Cost Basis	Sell Price	Total Return	Status	
CYTIER THERAPEUTICS	CYT	01-09-2024	\$3.05	\$3.12	2.30%	Sold February 8, 2024

*Disclaimer: this hypothetical portfolio should not be considered investment advice or a recommendation to buy/sell any financial instrument. For informational purposes only. Investors should perform their own due diligence before buying or selling any financial instrument. No express or implied guarantee of accuracy or applicability to real-world trading. Cost basis refers to the closing price the day before a security is recommended.*

*\*Sold 1/2 of Sagimet Bio (SGMT) on January 22, 2024 for a 231.29% gain. Recommended resuming a full position on February 8, 2024, up to \$6.75 per share.*

Beyond the specific developments we've covered in our prior updates on [Iovance Therapeutics](#) and [Sagimet Biosciences](#), there's no material news to discuss about other names in our portfolio.

Nonetheless, I'm mindful that the [Biotech Frontiers portfolio](#) as a whole – assuming you equal-weighted our buy recommendations – is up about 40% since we launched less than two months ago.

I think we have more gains to come... but that's still a lot of paper profit in a short time. I am not a short-term trader by practice nor by temperament. Quite the opposite: I'm prepared to hold investments for many years and believe the best investments *should* be held effectively forever, even passing them on intergenerationally. However, I've learned through painful experience in biotech that it's sometimes prudent to ring the cash register and take profit.

So, over the coming days and weeks, I'll be giving careful thought to whether we should be pruning some of our gains. You can count on me to share these reflections when they're fully formed.

That's all for this month.

Until soon, best regards



Erez

## **Ask Erez Anything... a Special Event Exclusively for Biotech Frontiers Subscribers**

Do you have questions for Erez about biotech, investing, or the economy? Now's your opportunity to ask him anything on these topics.

As a regular reader of *Porter & Co. Biotech Frontiers*, you likely have questions about biotech in general or individual stocks in particular... To help subscribers with all of these concerns, Erez will make himself available in Erez's Open Forum on Biotech later in March... To submit questions for Erez to answer during that video forum, which is open to all subscribers, email them to [erez@porterandcompanyresearch.com](mailto:erez@porterandcompanyresearch.com).

This is a great opportunity to meet Erez and have him specifically answer your questions... about anything related to biotech.

Details about the forum itself will arrive in your inbox in the coming weeks. And please understand that while Erez will answer questions as best he can on a variety of topics, he is unable to give individual investment advice.

(Please continue to send technical- and subscription-related issues to [support@porterandcompanyresearch.com](mailto:support@porterandcompanyresearch.com)).