

Hey, biotech buffs! Don't let the latest biotech news catch you by surprise!



White Paper by buyingsimplified.com

15 min Takeaway for Busy Finance Executives!

Curated by top experts, analysis and news from the world of biotech

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Biotech Buzz – The 3 Must-Know Headlines of the Month

Explore the Most Exciting Biotech Breakthroughs with us.

1 Biotech's Big 3 M&A Targets to Watch in 2023

Athira Pharma

What's going on:

Athira Pharma is developing a drug for Alzheimer's disease and is currently in a phase 2/3 study with a readout in early 2024.

The company faced challenges in 2022, including a phase 2 flop and a proxy fight against an investor.

Despite these challenges, there is growing interest in the company, as management has had numerous meetings with investors and strategics.

Why do I care:

As a CFO of a biopharma company, it's important to stay informed about developments in the industry.

Athira Pharma's drug development for Alzheimer's disease is an example of the type of work being done in the space.

Understanding the challenges faced by companies like Athira can inform decision-making and strategy for other biopharma companies.

Athira's management had "75 or more" meetings with investors and strategics, indicating growing interest in the company.



Bigger picture –

Zoom in:

The biopharma industry is seeing renewed interest in Alzheimer's drug development after the approval of Leqembi in 2022.

Athira Pharma is developing fosgonimeton for mild to moderate Alzheimer's disease, as well as for Parkinson's disease dementia and Lewy body dementia.

Zoom out:

The company faced challenges in 2022 but is still moving forward with its pipeline and has generated interest from investors and strategics.

360-degree perspective:

Athira Pharma's drug development for Alzheimer's disease is one piece of a larger puzzle in the biopharma industry.

As a CFO, it's important to consider the company's pipeline and challenges within the context of the industry as a whole.

Understanding the interests of investors and strategics can provide insight into the company's potential future opportunities and challenges.

What's going on:

- Icosavax's VLP technology has been gaining attention for its potential to create stronger immune responses.
- The technology initially received criticism after underwhelming data from the company's COVID-19 vaccine in March 2022.
- However, phase 1 data for IVX-121 showed promising results, restoring faith in the VLP platform.
- Icosavax's CEO is optimistic about the technology's potential.

Why do I care:

- Icosavax's VLP technology has the potential to create stronger immune responses than other vaccine platforms.
- The technology could be applied to a variety of diseases, including RSV and human metapneumovirus.
- If IVX-A12's phase 1 trials are successful, it could further cement Icosavax's reputation.
- The company has an affordable \$400 million market cap.

Bigger picture –

Zoom in:

- Icosavax's VLP technology is gaining attention for its potential to create stronger immune responses, which could have significant implications for vaccine development.
- Phase 1 data for IVX-121 showed sustained immunologic response at six months, suggesting the technology's durability lives up to the hype.

Zoom out:

- IVX-A12's phase 1 trials will provide further insight into the technology's potential for other diseases.

360-degree perspective:

- Icosavax's VLP technology has been gaining attention and could potentially revolutionize vaccine development.
- The technology has faced some criticism after underwhelming data for its COVID-19 vaccine, but phase 1 data for IVX-121 showed promising results.
- The company has another vaccine in phase 1 trials, with a top-line readout expected in mid-2023.
- With an affordable market cap, Icosavax has the potential to be an attractive acquisition target for larger pharmaceutical companies.



ICOSAVAX



What's going on:

- Karuna Therapeutics is generating hype for its KarXT candidate, which showed success in treating schizophrenia and psychosis symptoms in a phase 3 trial.
- Mizuho analysts have called KarXT a potential "gamechanger" with predicted global peak sales of \$6.8 billion across several indications.
- Karuna plans to file for FDA approval for KarXT in mid-2023 and has ongoing phase 3 trials assessing the drug's effects on acute psychotic symptoms or safety over a year.
- The company also has a phase 3 trial evaluating KarXT for psychosis related to Alzheimer's disease.

Why do I care:

- KarXT has shown promising results in treating schizophrenia and psychosis symptoms, which could potentially revolutionize the treatment paradigm in psychiatry.
- The drug has multiple ongoing phase 3 trials and could receive FDA approval in mid-2023, making it a potential investment opportunity.

Bigger picture –

Zoom in:

- Karuna Therapeutics has developed a potential revolutionary therapy for treating schizophrenia and psychosis symptoms with its KarXT candidate.

Zoom out:

- Karuna's stock price has doubled since the success of its phase 3 trial, resulting in a market cap of \$7 billion.

360-degree perspective:

- Karuna Therapeutics has promising potential in the development of KarXT, a potentially revolutionary therapy for schizophrenia and psychosis symptoms.
- However, it remains to be seen if a Big Pharma will make an offer for Karuna or if the company will choose to launch KarXT on its own, as it currently has \$1.2 billion in cash and equivalents.

In our upcoming newsletter, we'll reveal the remaining M&A targets of 2023, ensuring you stay in the know.

Subscribe now to catch the next edition and receive exclusive updates on the latest and most promising biotech partnerships and acquisitions.



2 Top 5 most anticipated drug launches of 2023.

1

Drug: Lecanemab/Leqembi

Companies: Eisai/Biogen

Used for: Alzheimer's disease

Sales: Est. 2028 sales: \$3 billion

Mechanism:

- Works by removing amyloids, a protein that builds up in the brain and is believed to be a culprit behind Alzheimer's.

Challenges:

- Murky waters due to FDA and Biogen's controversial approval of Aduhelm, which was a commercial flop with high price and questionable safety and efficacy.
- FDA's reputation questioned after ignoring advice to reject Aduhelm and its "inappropriate" communications with Biogen regarding approval.
- Safety concerns due to two trial patient deaths, though Eisai denies drug responsibility.
- Questions on meaningfulness of 27% slowing of disease progression.



Top 10 most anticipated drug launches of 2023

2

Drug: SRP-9001

Companies: Sarepta/Roche

Used for: Gene therapy for Duchenne muscular dystrophy

Sales: Estimated 2028 sales of \$2.2 billion

Mechanism:

- Designed to deliver the microdystrophin-encoding gene into muscle tissue to prompt production of the microdystrophin protein

Challenges:

- U.S. commercial success for SRP-9001 is by no means guaranteed
- Securing full reimbursement in the U.S. is likely to take time
- Safety and long-term efficacy of gene therapy are still uncertain
- Gene therapies will be expensive to make and use, and pricing will be an issue
- Lack of precedents in the new therapy area makes predicting demand difficult
- Reimbursement for an expensive product will be a problem

FDA
ADCOMM

delandistrogene moxeparvovec (SRP-9001)



Top 10 most anticipated drug launches of 2023

3

Drug: Intravitreal pegcetacoplan

Company: Apellis

Used for: Complement factor C3 inhibitor for geographic atrophy

Estimated sales: \$2 billion by 2028

Potential market: 1 million Americans with geographic atrophy

Potential peak annual sales: \$3 billion

Challenges:

- Geographic atrophy has no FDA-approved treatments
- Previous efforts to treat geographic atrophy have failed
- Risk of Apellis facing similar challenges
- Internal issues, including changes to FDA review process, have caused investor concern
- Clinical trial data for pegcetacoplan's efficacy in treating geographic atrophy is uncertain
- Uncertainty around whether an advisory committee will be formed for the drug's approval
- Potential competition from Iveric Bio's C5 agent Zimura

Mechanism:

- Pegcetacoplan is a complement factor C3 inhibitor
- Pegcetacoplan is already approved as Empaveli for paroxysmal nocturnal hemoglobinuria



Top 10 most anticipated drug launches of 2023

4

Drug: Donanemab

Company: Eli Lilly

Used for: Anti-amyloid monoclonal antibody for Alzheimer's disease

Sales: Estimated 2028 sales of \$1.9 billion

Downgraded from last year's prediction of \$6 billion by 2026

Challenges:

- Delayed FDA approval due to the need for longer data on patients using the drug
- Clinical hits and misses, with a slight win on one disease scale and a failure on another
- Mixed results from 2021 data showing a significant slowing of decline in Alzheimer's patients, but a failure on a commonly used scale to diagnose dementia due to Alzheimer's
- FDA's willingness to approve more drugs for Alzheimer's disease may be auspicious for Lilly

Mechanism:

- Reduces brain amyloid plaque levels by 65.2% at six months compared to baseline, according to head-to-head trial against Aduhelm
- Lilly is now planning for a "traditional approval" with the FDA by midyear

The Lilly logo is written in a red, cursive script font.

Top 10 most anticipated drug launches of 2023

5

Drug: RSVPreF3 OA

Company: GSK

Used for: Vaccine for older adults for respiratory syncytial virus

Sales: Estimated 2028 sales of \$ 1.8 Billion

Resources:

GSK's vaccine showed statistically significant and clinically meaningful reductions in cases of lower respiratory tract disease caused by RSV in adults aged 60 years and older

Pfizer, Moderna, and J&J are also developing RSV vaccines

Challenges:

Previous attempts at RSV vaccines have faced setbacks and flops

GSK had to abandon plans to develop a vaccine for infants due to safety concerns in its maternal vaccine trial

GSK will face competition from Pfizer, Moderna, and J&J in the RSV vaccine market

Mechanism:

RSV is a respiratory virus that can cause serious complications and sometimes be fatal in vulnerable populations such as the elderly and children under 5

GSK's RSVPreF3 OA vaccine aims to prevent cases of lower respiratory tract disease caused by RSV in adults aged 60 years and older.



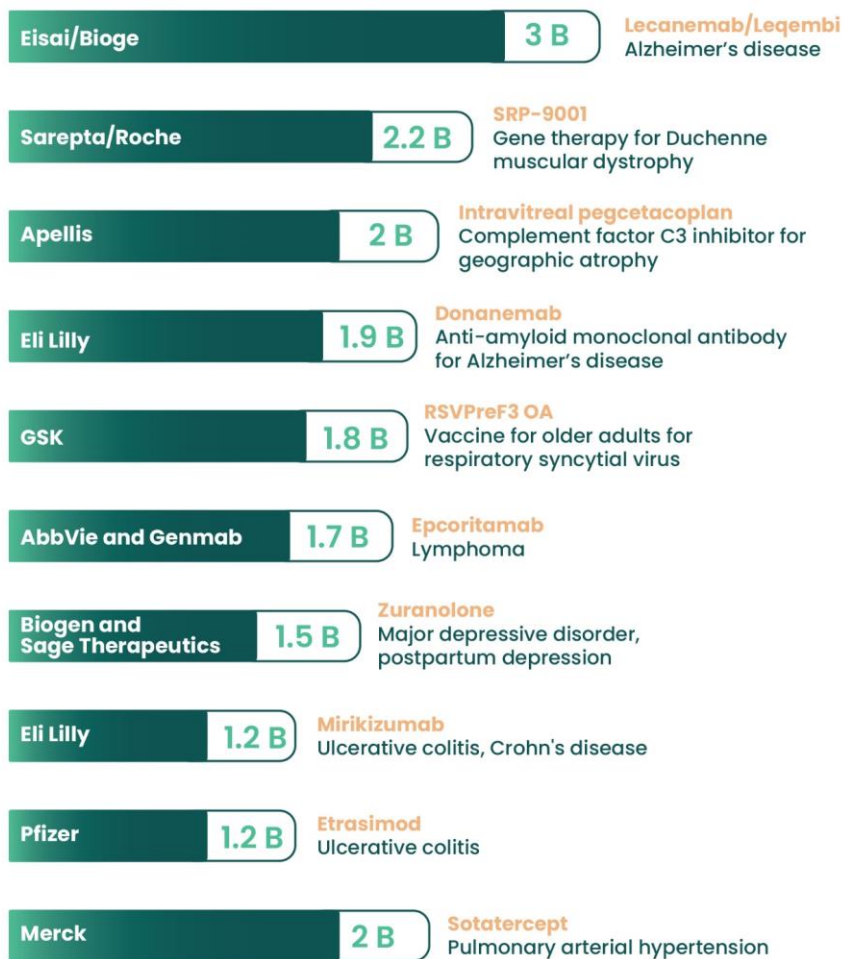
Stay ahead of the curve with our newsletter! In the upcoming edition, we'll unveil the next 5 incredible drug launches of 2023.

Don't miss out on this exclusive update - [Subscribe now](#) to get the latest details delivered right to your inbox!



Estimated Sales 2028

Top 10 drugs of 2023



■ Estimated sales ■ Drug name

Figure: The presented graph highlights the projected top 10 drug sales for the year 2028, categorized by various diseases. The data showcases the estimated revenue potential of these drugs, indicating the significant impact they are expected to have on the healthcare industry in the coming years. This information provides valuable insights for healthcare stakeholders and investors, allowing them to make informed decisions and allocate resources accordingly.

3 Biotech Financing Roundup 2023!

The biotech industry in 2023 has seen a significant amount of funding from a diverse range of sources, indicating strong investor confidence in the potential for growth and innovation in this sector.

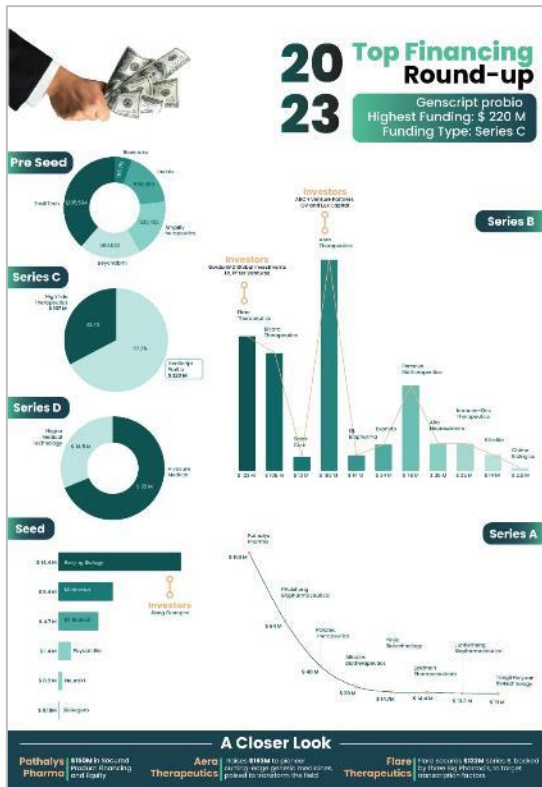


Figure: Please see next page for details

Big Picture:

GenScript ProBio has raised a total of \$220M in funding over 1 round. This was a Series C round raised on Jan 18, 2023. It is funded by 8 investors. China Industrial Asset Management and Hillhouse Capital Group are the most recent investors.

Flare Therapeutics announced the successful closure of its Series B funding round, which raised \$123 million. The company intends to use these funds to further develop its lead precision oncology asset, FX-909, specifically for the treatment of urothelial cancer. The funding round was oversubscribed, indicating strong investor interest in Flare Therapeutics' potential for growth and innovation in the oncology sector.

Pathalys Pharma has recently secured \$150 million in funding. The funds will be used to support phase 3 clinical trials for the company's primary drug candidate, which is being developed to treat end-stage kidney disease. This financing represents a significant milestone for Pathalys Pharma, indicating investor confidence in the potential of its drug candidate to address a critical unmet medical need in the treatment of kidney disease.

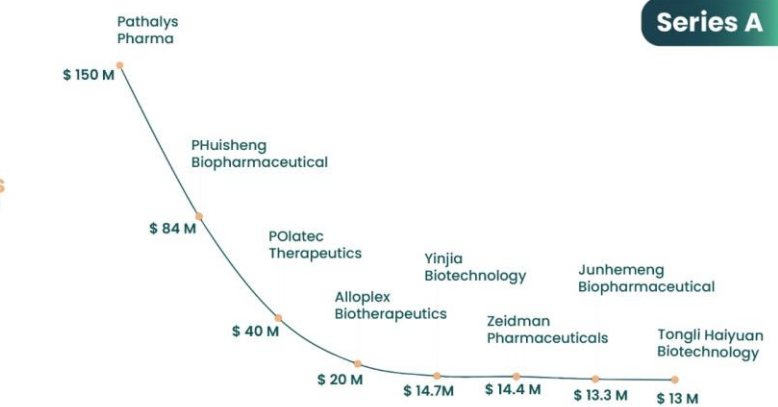
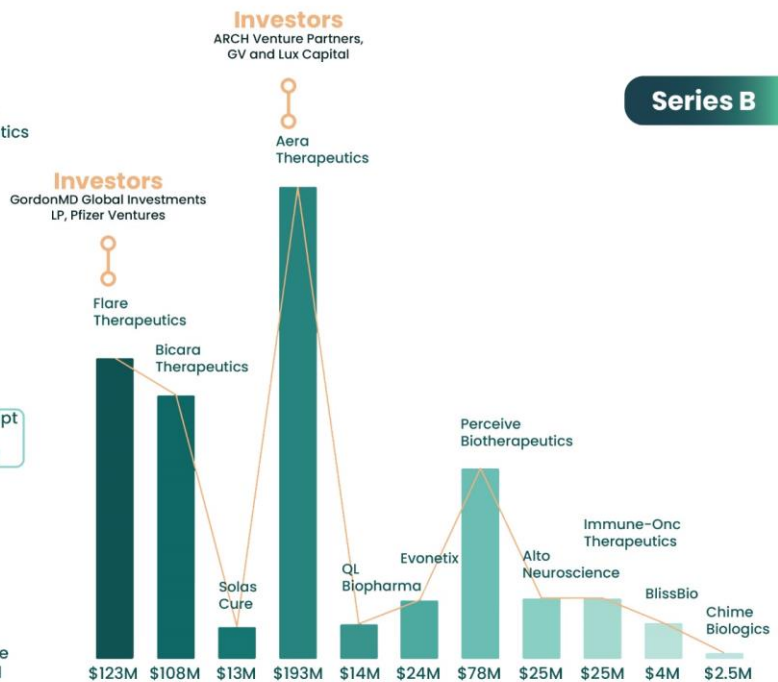
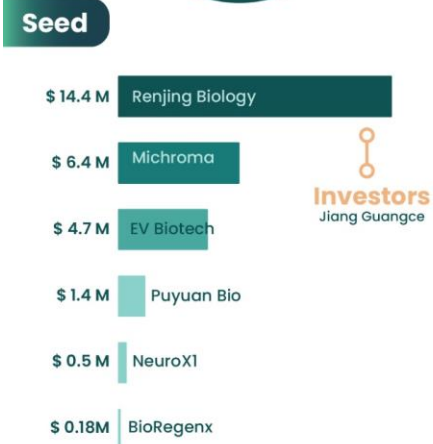
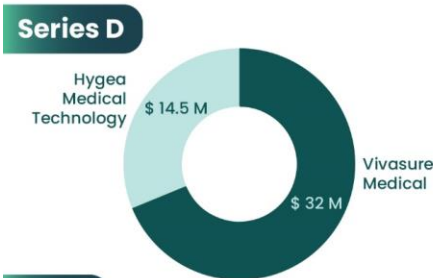
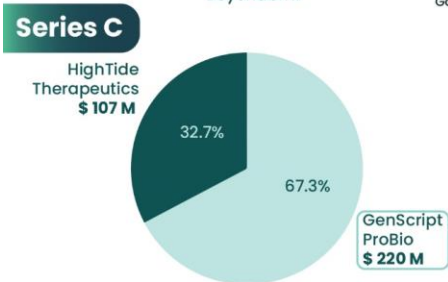
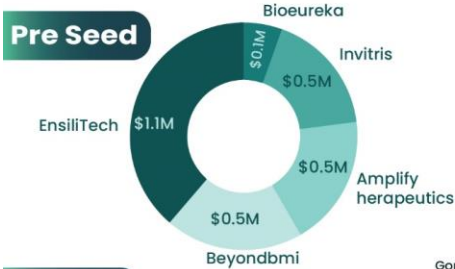
Aera Therapeutics has successfully raised a total of \$193 million in combined Series A and B financings. Led by ARCH Venture Partners, GV, and Lux Capital, the funding will be used to expand the company's operations and accelerate its development efforts. Aera Therapeutics is focused on providing a proprietary protein nanoparticle delivery platform, and this significant investment underscores investor confidence in the company's potential for growth and innovation in the biotech industry.



20 Top Financing Round-up

23

GenScript probio
Highest Funding: \$ 220 M
Funding Type: Series C



A Closer Look

Pathalys Pharma | \$150M in Secured Product Financing and Equity

Aera Therapeutics | Raises \$193M to pioneer cutting-edge genetic medicines, poised to transform the field

Flare Therapeutics | Flare secures \$123M series B, backed by three Big Pharma's, to target transcription factors.

Figure: The presented graphs illustrate the various types and amounts of funding that biotech companies have received, showcasing the diversity and scale of investment in this industry. This data highlights the continued interest and support from venture capitalists, private equity firms, strategic partners etc, emphasizing the significant role that funding plays in driving innovation and growth within the biotech sector.

A look at Biotech investment – Top 10!

Company Name	Funding Type	Funding Amount	Investors Name
GenScript ProBio	Series C	220 M	<i>Highlight Capital, Hillhouse Capital Group, Huatai Zijin Investment</i>
Aera Therapeutics	Series B	193 M	<i>ARCH Venture Partners, Google Ventures, Lux Capital</i>
Pathalys Pharma	Series A	150 M	<i>Abingworth, Catalys Pacific, DaVita Venture Group</i>
Flare Therapeutics	Series B	123 M	<i>Agent Capital, Boxer Capital, Casdin Capital</i>
Bicara Therapeutics	Series B	108 M	<i>Acorn Bioventures, Bioqube Ventures, Eight Roads Ventures</i>
HighTide Therapeutics	Series C	107 M	<i>China Development Bank Capital, Guangzhou Yuexiu Industrial Investment Fund, Yuthai Fund</i>
Huisheng Biopharmaceutical	Series A	84 M	<i>Baixing Bairong, Changchun Equity Investment Fund Management, JiLin Province Private Equity</i>
Perceive Biotherapeutics	Series B	78 M	<i>Braidwell, Catalio Capital Management, Deerfield,</i>
Olatec Therapeutics	Series A	40 M	<i>Advection Growth Capital, Sanders Morris Harris</i>
Vivasure Medical	Series D	32 M	<i>Haemonetics</i>

Want to know who's investing in the hottest companies on the rise?

Click below to get the names of the investors and all the juicy details on the next 20+ biotech giants valued at \$240M!

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Tips and tools for accurate Financial Planning & Analysis

Sl No.		Formula	Function
1	Custom keyboard shortcuts	(File > Options > Customize Ribbon > Keyboard Shortcuts) Assign a keyboard shortcut to a command, such as CTRL + Shift + C, for copy formula.	Excel automatically copies the formula from the selected cell to the destination cells.
2	Conditional formatting	Highlight cells that meet a specific condition, such as values greater than 100. Home > Conditional Formatting > Highlight Cells Rules > Greater Than and enter "100" as the value.	Cells with values greater than 100 are highlighted in red.
3	Pivot tables	=PIVOT(TABLE)(data range,[field1],[field2],...)	The function of a Pivot Table is to summarize, analyze, and present large amounts of data in a meaningful and interactive way. It lets users filter, sort, and group data based on variables such as time periods, products, categories, or regions.
4	Data validation	(Data > Data Validation) Select cell A1, go to Data > Data Validation > Allow: List, and enter "=Table1[Product]" as the source.	Create a dropdown list in cell A1 that allows the user to select a product name from a table. This is useful for preventing errors caused by typing mistakes or incorrect data entry.
5	Freeze panes	(View > Freeze Panes) Freeze the top row to keep headings visible while scrolling through large datasets.	The top row remains visible as the user scrolls through the rest of the data.
6	XLOOKUP	=XLOOKUP (lookup_value, lookup_array, return_array, [if_not_found], [match_mode], [search_mode])	An improved version of the VLOOKUP and HLOOKUP formulas is commonly used in financial modelling. It allows you to search for a specific value in a table and return the corresponding value from another column in the same row.
7	IF & COUNTIF function	(=COUNTIF (A1:A10, "condition")) & (=IF (condition, actual value, false value))	The COUNTIF function in Excel counts the number of cells within a specified range that meet certain criteria or condition. The IF function returns a different value based on whether the logical test is true or false.
8	AVERAGE function	(=AVERAGE (A1:A10))	The AVERAGE function returns the average sales for the specified product.
9	MAX/MIN functions	(=MAX (A1:A10) or =MIN (A1:A10))	The MAX and MIN functions in Excel are used to find the highest and lowest values in a range of cells, respectively.
10	TEXT Function	(=TEXT (value, "format"))	The TEXT function in Excel is used to convert a numeric value into a formatted text string. It can format dates, times, currencies, percentages, and other values.

We bring you the best practices, tips, and tricks to help you master your finances and stay on top.

Supply Chain Spotlight

Cost-Saving Strategies: CFOs Forge Strong Business Partnerships with Supply Chain Leaders

1 Try spending time for the supply chain (Time is Money)



How can CFOs establish a strong and effective partnership with the supply chain?

CFOs should spend at least 20–25% of their time working with the supply chain to foster collaboration and ensure alignment.

Success Pathway:

- Work closely with supply chain teams to develop a clear understanding of the supply chain's key drivers and risks.
- Identify opportunities for cost savings and efficiency improvements within the supply chain.
- Establish regular communication channels with supply chain stakeholders to monitor performance and collaborate on strategic initiatives.
- Work with the supply chain to develop a comprehensive risk management strategy that considers potential disruptions to the supply chain.
- Encourage cross-functional collaboration and communication between the finance and supply chain teams.
- Support the development of technology and tools that can help optimize the supply chain and enhance financial performance.
- Foster a culture of continuous improvement within the supply chain and across the organization.

2 Allocate finance resources to the supply chain

How can finance support the supply chain?

By embedding finance business partners in the supply chain, with a hard reporting line back to finance and a dotted reporting line into the functional head.

SUCCESS PATHWAY:

- Allocate resources to support supply chain initiatives and investments, such as implementing new technology or expanding into new markets.
- Develop a robust financial analysis framework that enables the supply chain team to evaluate the costs and benefits of different options and make data-driven decisions.
- Provide guidance on financial metrics that are relevant to the supply chain, such as inventory turnover, cash-to-cash cycle time, and working capital management.
- Establish financial controls and risk management processes that mitigate financial risks within the supply chain, such as supplier defaults or supply chain disruptions.
- Collaborate with the supply chain team to develop and implement a budget that aligns with the organization's strategic goals and objectives.
- Monitor and analyse financial performance data to identify areas where the supply chain can improve performance or reduce costs.
- Provide training and education to the supply chain team on financial management and analysis, to enable them to make better financial decisions and understand the impact of their actions on the organization's overall financial performance.



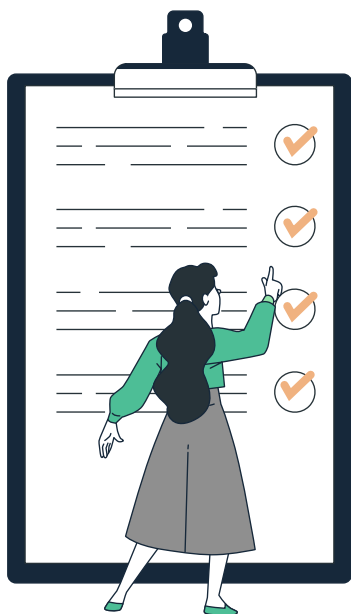
3 Participate in the sales and operations planning process

How can CFOs provide value to the S&OP process?

By providing insight and information to help ensure alignment across functions and with the broader strategy.

Success pathway:

- Align the S&OP process with strategic goals and financial objectives
- Provide financial insights and guidance to the S&OP team
- Develop and implement a comprehensive budget and contingency plan
- Monitor financial performance and identify areas for improvement
- Foster cross-functional collaboration and communication
- Provide financial training and education to the S&OP team



4 Own your organization's data



How can CFOs prevent inconsistent data driving decisions?

By taking ownership of data and presenting a single version of the truth.

Success pathway:

- Establish clear data governance policies and procedures that ensure data accuracy, completeness, and consistency.
- Work with IT and data management teams to implement data quality controls and validation checks.
- Develop a centralized data repository that stores all relevant data in a standardized format.
- Use data visualization and analytics tools to identify and resolve inconsistencies in data.
- Encourage cross-functional collaboration and communication to ensure that data is consistent across departments.
- Provide training and education to employees on data management best practices and how to use data to make informed decisions.
- Establish a data governance committee or team that includes representatives from across the organization to oversee data quality and consistency.
- Develop a process for regularly reviewing and updating data to ensure that it remains accurate and up to date.

5 Stay involved throughout the investment cycle

How can CFOs help strengthen the business case for investments?

By being involved throughout the investment life cycle, from choosing an asset for investment through to managing its performance, retiring it, or reinvesting in it.



Success pathway:

Work with the supply chain team to develop a comprehensive implementation plan that considers all aspects of the investment, including supply chain logistics, production processes, and customer demand.

Provide guidance on financing options, such as debt financing or equity financing, and help the supply chain team develop a financing strategy that aligns with the organization's overall financial goals.

Collaborate with the supply chain team to develop a business case that outlines the investment's objectives, benefits, risks, and implementation plan.

Present the business case to key stakeholders, such as the executive team or board of directors, and provide financial insights to support the investment decision.

6 Help build an integrated operating model

How can CFOs build an integrated, cost-efficient, effective structure?

CFOs and supply chain leaders can build an integrated operating model that puts the company in a better position to create shareholder value.



Success pathway:

Three layers: physical structures such as facilities and equipment, people including talent and skills, and organizational structures such as reporting lines and decision-making processes. Also need to consider indirect taxes, transfer pricing, the effective tax rate, and legal structures as part of this approach.

By addressing all these layers, CFOs and supply chain leaders can work together to build an operating model that is cost-efficient, effective, and aligned with the company's overall strategy and goals.

This can help improve performance, enhance shareholder value, and provide a competitive advantage in the marketplace.

7 Focus the supply chain on the metrics that matter

How can CFOs ensure clarity around the real objectives of the organization?

Work with supply chain leaders to identify the most important metrics that will drive performance and support the achievement of the organization's goals.

- Avoid the temptation to measure everything, and instead focus on a few key metrics that are truly meaningful and actionable.
- Ensure that the metrics selected are aligned with the organization's overall strategy, and that they provide a clear line of sight between supply chain performance and business results.
- Implement an effective performance management system that tracks progress toward the selected metrics and provides regular feedback to supply chain leaders on performance.



8 Identify performance incentive misalignment

How can CFOs ensure alignment of incentives to meet the objectives of the business?

CFOs should ensure that incentives align with the overall objectives of the business, rather than just those of individual functions.

- Work with cross-functional teams to identify the specific incentives that will drive performance and support the achievement of the organization's goals.
- Avoid the temptation to focus solely on short-term incentives, and instead design incentives that support long-term success.
- Ensure that incentives are consistent with the organization's values and culture, and that they promote collaboration and teamwork.

9 Consider centralizing business functions

How can CFOs achieve economies of scale?

By centralizing key business functions such as procurement, the supply chain can benefit from increased efficiency and streamlined processes, reducing the time and resources required to manage these functions.

- A centralized operating model can provide greater visibility into supply chain operations and performance, allowing for more informed decision-making and improved collaboration across teams.
- Also, can help to better manage risks and minimize disruptions, such as by having a centralized procurement team that can quickly respond to supply chain disruptions or changes in demand.



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10 Look deep in the supply chain for risks

How can CFOs identify and mitigate risks in the supply chain?

By gaining visibility into secondary and tertiary layers of the supply chain and ensuring appropriate control over external partners.

- To identify potential risks in the supply chain, CFOs should conduct a thorough risk assessment that includes an evaluation of all suppliers and partners, as well as an analysis of potential threats such as natural disasters, geopolitical instability, and regulatory changes.
- Many companies only have visibility into their first-tier suppliers, but risks can exist at deeper levels in the supply chain. CFOs should work with supply chain partners to gain visibility into secondary and tertiary layers of the supply chain to identify potential risks.



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Stay tuned and get ready to go global!

That's all for this month's newsletter - we hope you found it engaging and informative. As always, we welcome your feedback and suggestions for future content. Thanks for reading!

*Best Regards,
The Buying Simplified Team*

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