Biotech's Roadblocks to Normalization

BDO Biotech Brief
Autumn 2024

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Introduction

The biotechnology industry has worked rigorously to innovate and adapt to evolving trends, but not without experiencing challenges. Biotechs have faced resistance from weary investors navigating challenging macroeconomic conditions. Data analysis shows revenue and investment patterns vary across company sizes, with revenue plummets observed in small companies and soaring debt for large ones.

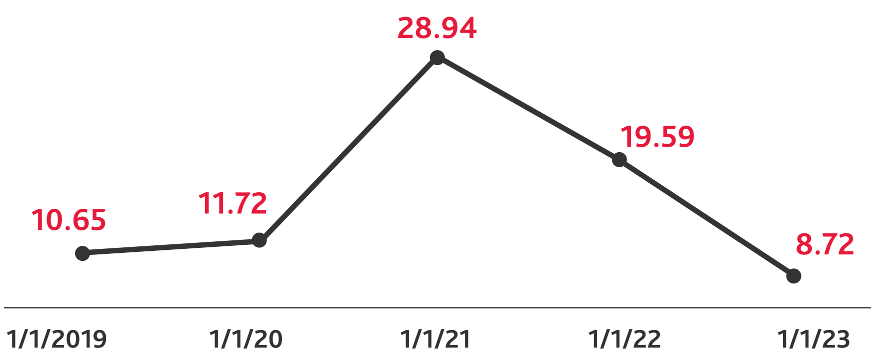
High interest rates have also plagued companies throughout the industry while several patent expirations and emerging drug pricing legislation has impeded growth for large biotechs. Some small companies have also been met with financial hardship after going public before they were ready during the pandemic's biotech boom.

Despite these challenges, some data indicates renewed confidence in the industry. Biotechs of all sizes are tackling their respective challenges in stride as they build stable and innovative businesses.

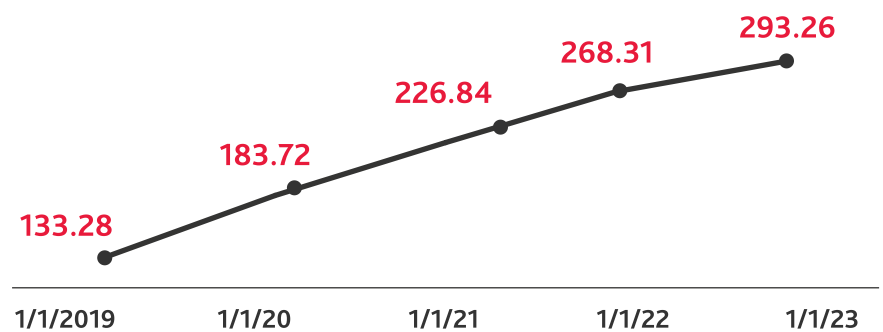
Biotech's Economic Dilemma

Biotechs saw another year of gradual change in revenue with a 3% decline overall and a 2% decline in cash and equivalents. However, when companies that produce COVID-19 vaccines and treatments are removed from the collected data, revenue jumps to an average increase of 8%, while average cash and equivalents reflect a 1% change.

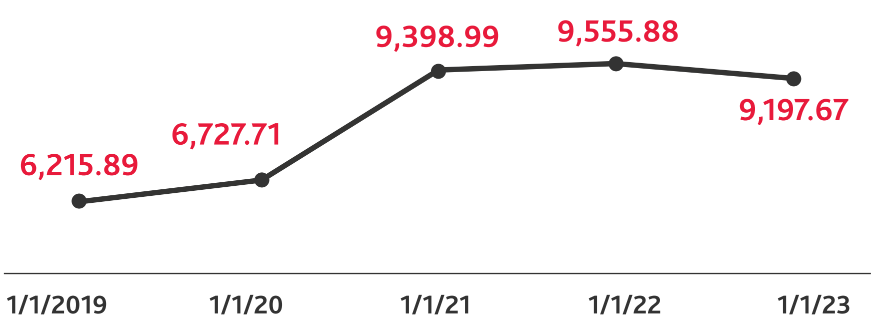
AVERAGE SMALL CAP REVENUE YoY



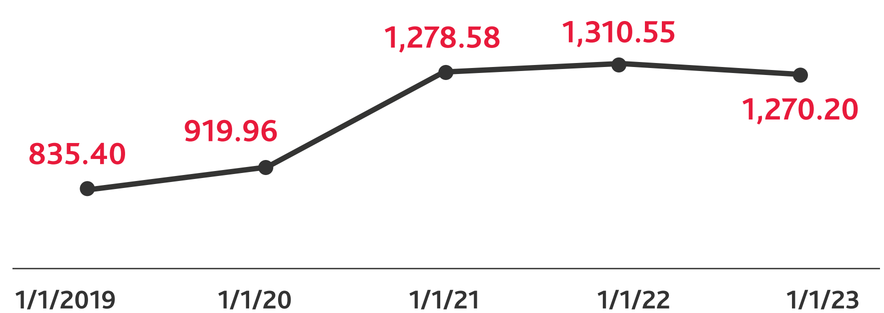
AVERAGE MEDIUM CAP REVENUE YoY

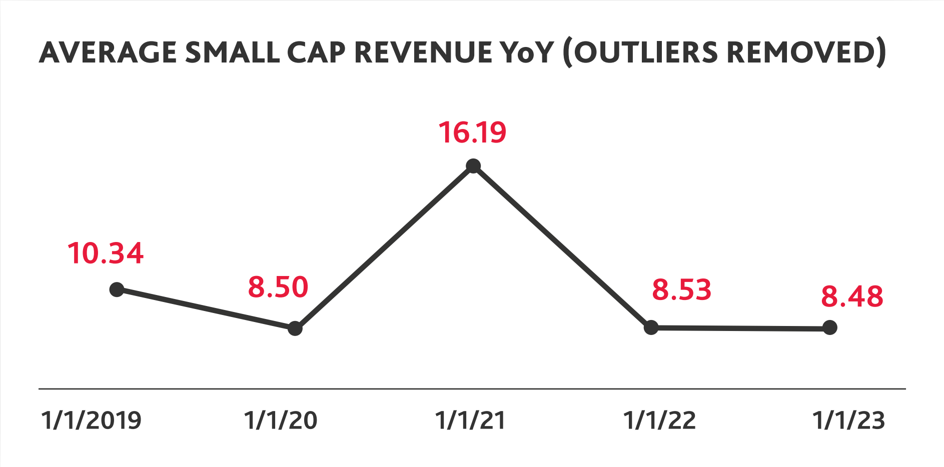


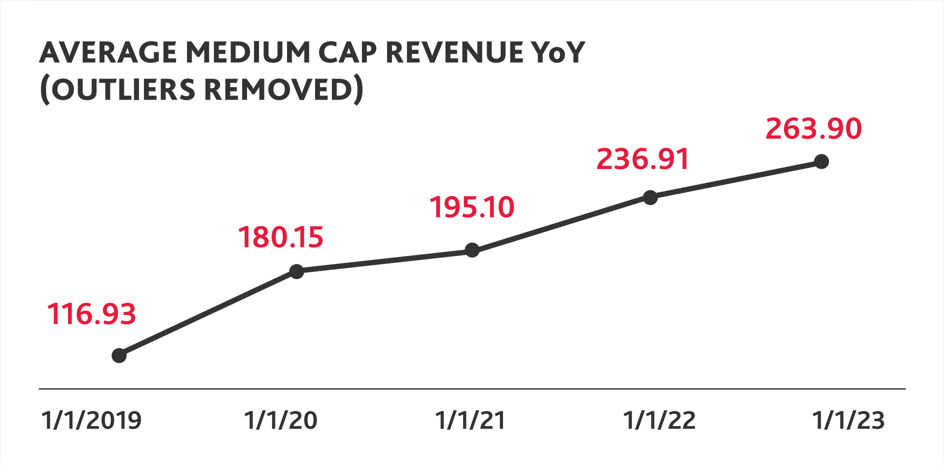
AVERAGE LARGE CAP REVENUE YoY

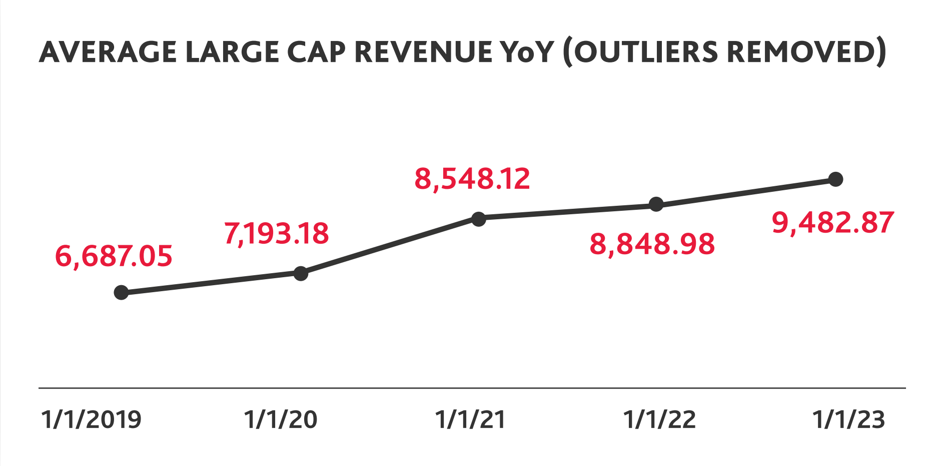


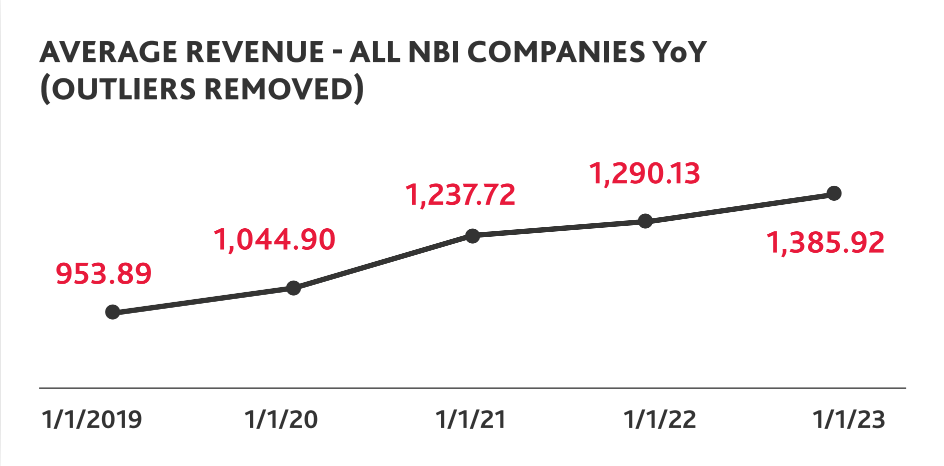
AVERAGE REVENUE - ALL NBI COMPANIES YoY

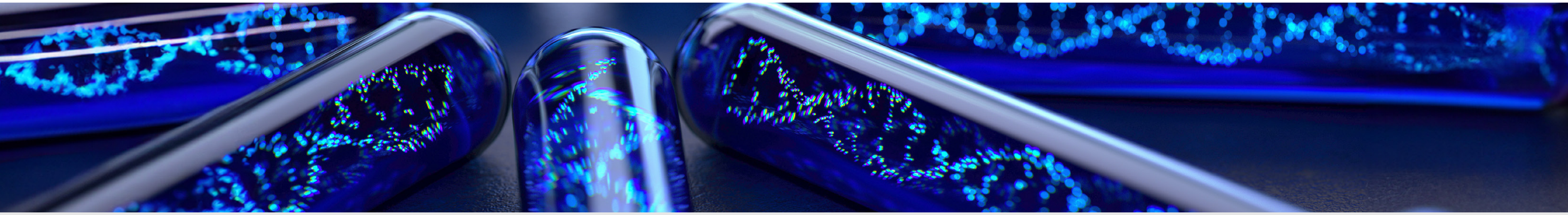



AVERAGE SMALL CAP REVENUE YoY (OUTLIERS REMOVED)
10.34
8.50
16.19
8.53
8.48
1/1/2019
1/1/20
1/1/21
1/1/22
1/1/23


AVERAGE MEDIUM CAP REVENUE YoY (OUTLIERS REMOVED)
116.93
180.15
195.10
236.91
263.90
1/1/2019
1/1/20
1/1/21
1/1/22
1/1/23


AVERAGE LARGE CAP REVENUE YoY (OUTLIERS REMOVED)
6,687.05
7,193.18
8,548.12
8,848.98
9,482.87
1/1/2019
1/1/20
1/1/21
1/1/22
1/1/23

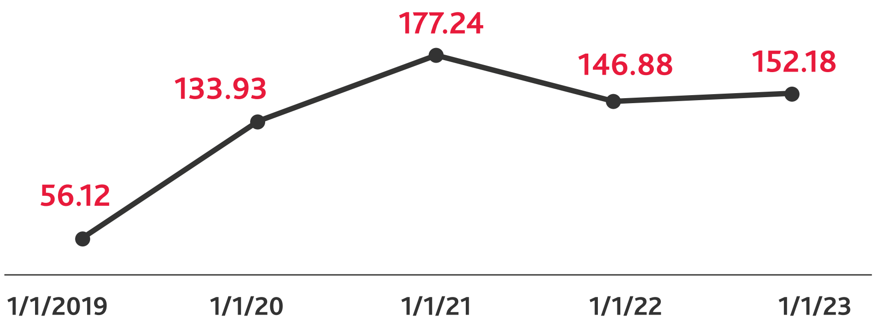

AVERAGE REVENUE - ALL NBI COMPANIES YoY (OUTLIERS REMOVED)
953.89
1,044.90
1,237.72
1,290.13
1,385.92
1/1/2019
1/1/20
1/1/21
1/1/22
1/1/23



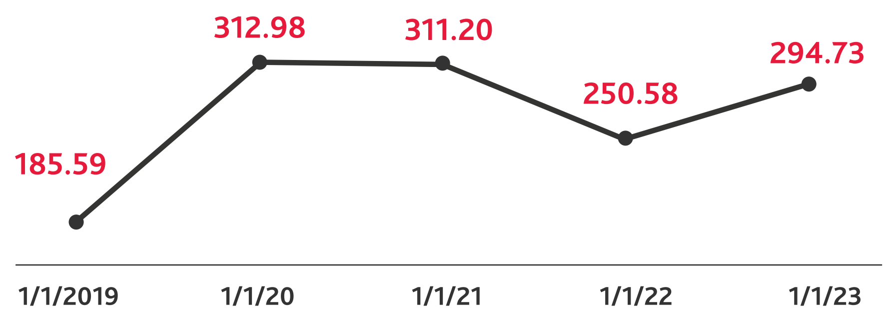
The revenue increase is mostly buoyed by advances in revenue among medium-cap companies due to recent product launches and increases in product sales, licenses and collaborations, while small companies saw a sharp decline in revenue of 55%. Much of the decline in small biotech revenue is due to significant prior year revenues from 10 companies resulting in an approximate $1.2 billion in revenues related to licensing, collaboration, or milestones that did not re-occur in 2023. In some cases, this revenue may have bumped a company into the medium-cap category, but without a consistent source of revenue, it fell back into the small-cap category in 2023.

Alternatively, medium-cap companies saw an overall increase in revenues and successful product launches. Now that the financing environment has become more competitive, struggling biotechs might face more difficulty staying afloat. The biotech industry could see a rebound if interest rates come down and the volume of financing deals returns, particularly for small biotechs that have been the most impacted by the higher cost of capital.

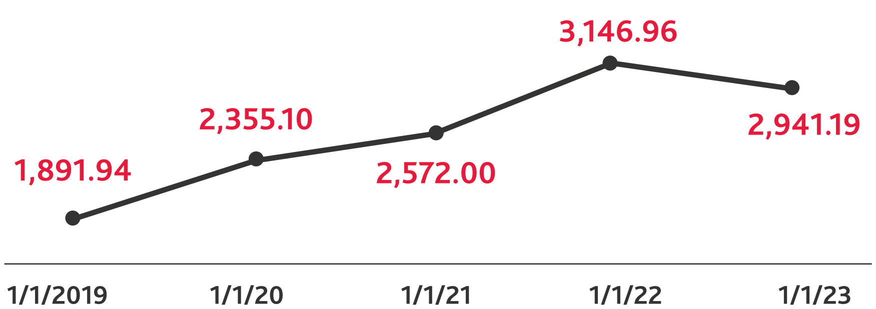
AVERAGE CASH AND EQUIVALENT CHANGES YoY FOR SMALL CAP COMPANIES



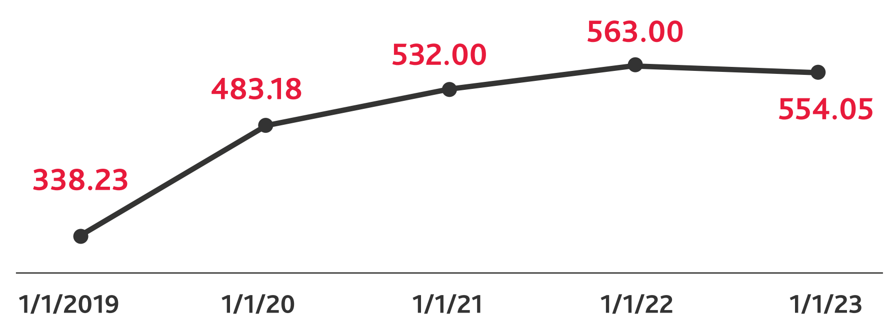
AVERAGE CASH AND EQUIVALENT CHANGES YoY FOR MEDIUM CAP COMPANIES



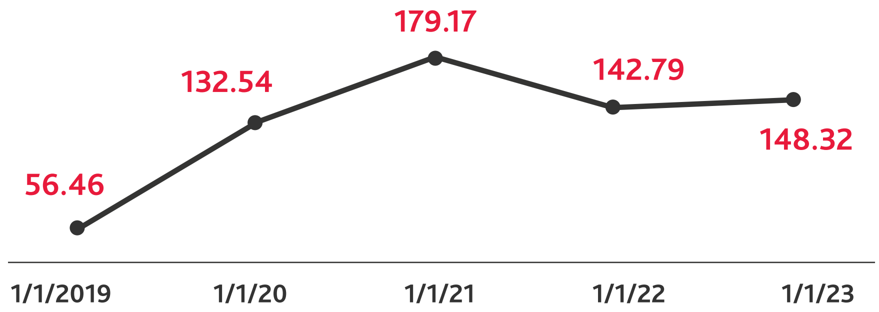
AVERAGE CASH AND EQUIVALENT CHANGES YoY FOR LARGE CAP COMPANIES



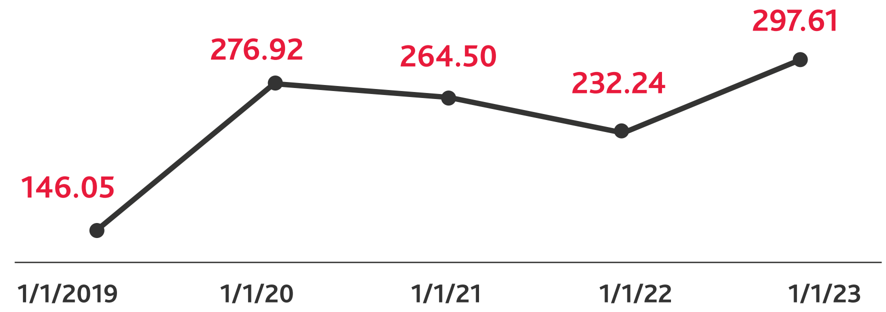
AVERAGE CASH AND EQUIVALENT CHANGES YoY FOR ALL NBI COMPANIES



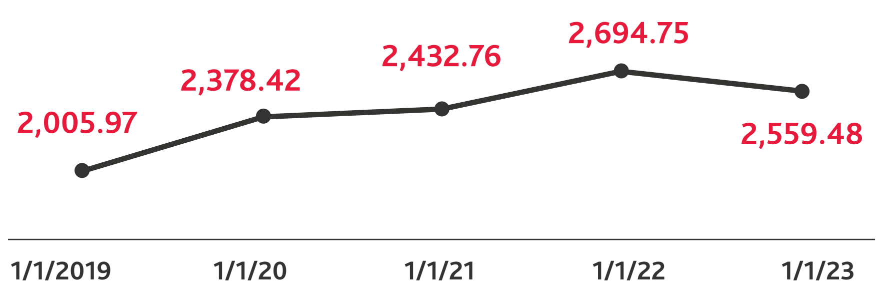
AVERAGE CASH AND EQUIVALENT CHANGES YoY FOR SMALL CAP COMPANIES (OUTLIERS REMOVED)



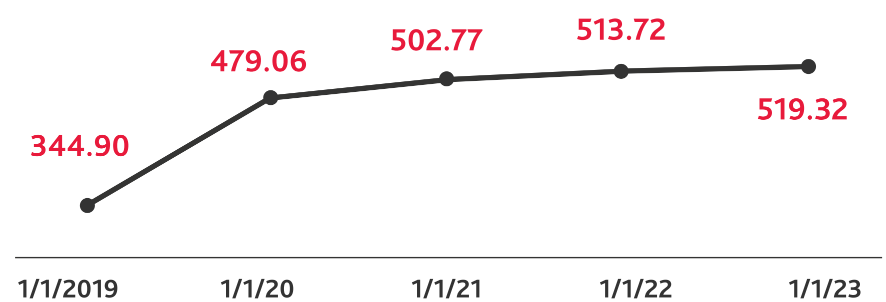
AVERAGE CASH AND EQUIVALENT CHANGES YoY FOR MEDIUM CAP COMPANIES (OUTLIERS REMOVED)



AVERAGE CASH AND EQUIVALENT CHANGES YoY FOR LARGE CAP COMPANIES (OUTLIERS REMOVED)



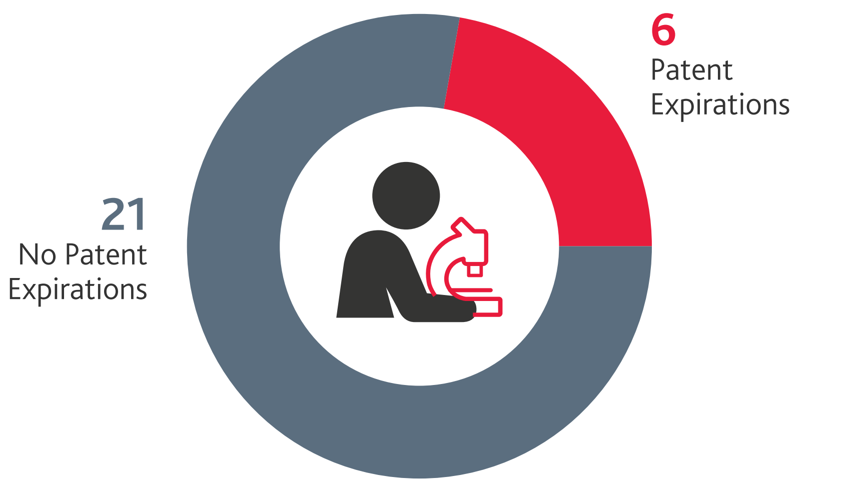
AVERAGE CASH AND EQUIVALENT CHANGES YoY FOR ALL NBI COMPANIES (OUTLIERS REMOVED)



Though declines in revenue and cash and equivalents for larger companies can be mostly attributed to the decline in sales of COVID-related drugs, evolving drug pricing legislation might also hinder future revenue. Expanding drug pricing regulations introduced in the Inflation Reduction Act, for example, will impact more companies over the next few years. The legislation will eventually affect up to 60 drugs covered under Medicare Part D and Part B, and up to an additional 20 drugs every year after that. Biotechs should pay attention to the legislative priorities of the new presidential administration in 2025 and be prepared to develop a strategy to mitigate lost revenue from drug pricing regulations.

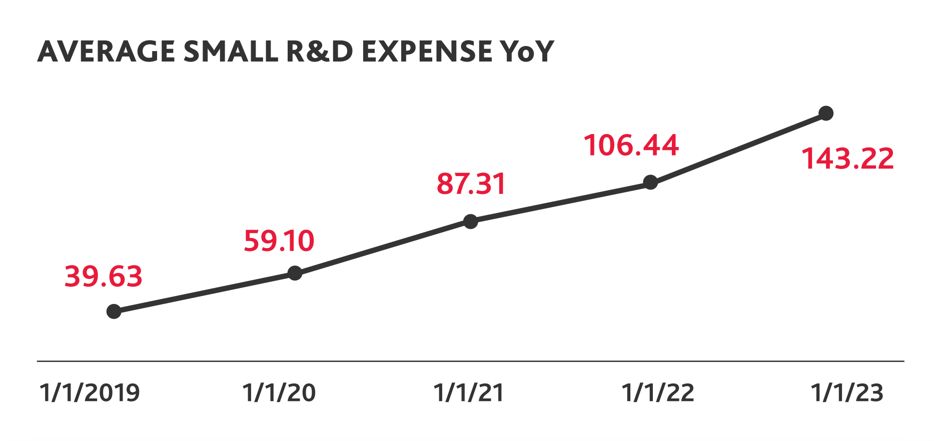
Revenue growth may also have stagnated due to several patent expirations that occurred last year, with roughly a quarter of large biotech companies experiencing at least one patent expiration in 2023, according to company press releases and quarterly earnings transcripts. As large biotechs work to develop and patent new drugs, it is not surprising that they increased their R&D spending (14%). The industry might also see more collaboration agreements and transactions as large companies either acquire or enter into agreements with smaller companies to provide a bulwark to expiring patents or changing pricing requirements.

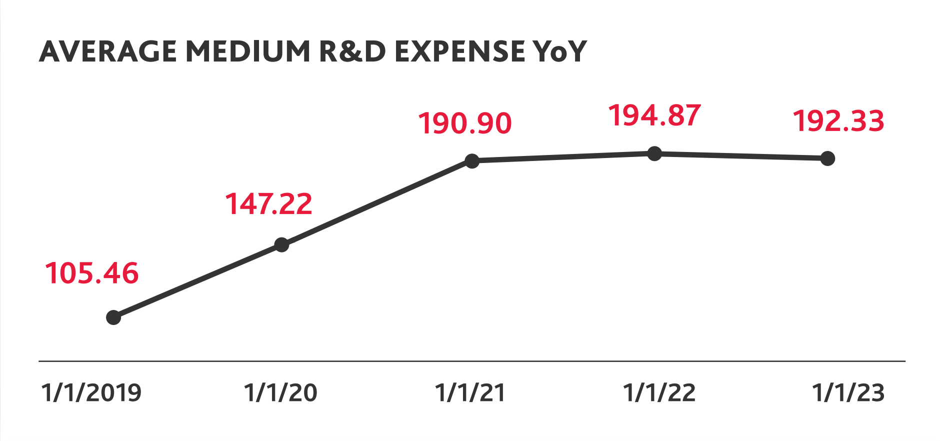
NUMBER OF LARGE CAP COMPANIES THAT LOST PATENT EXCLUSIVITY IN 2023

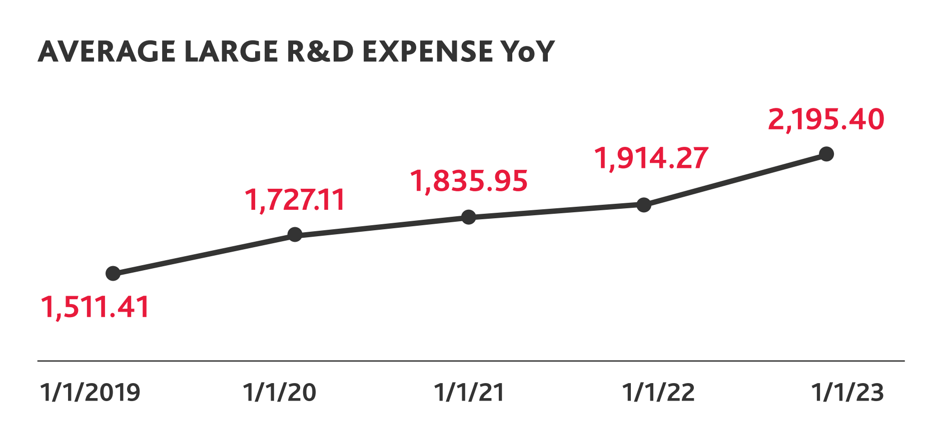


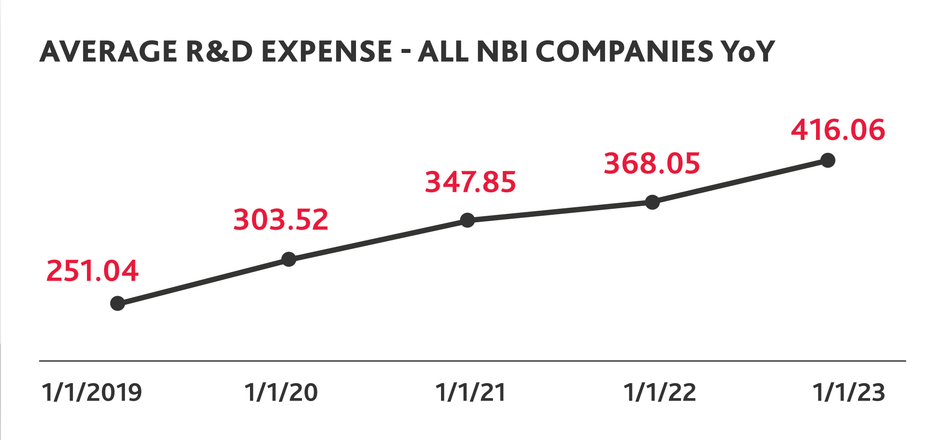
R&D on the Rise

Despite revenue declines in FY 2023 and inflation's impact on the cost of capital, labor, and materials, R&D spending saw a 13% increase — marking the fourth consecutive year of R&D spending increases. Increased investment in R&D is not only likely to usher in a potential wave of innovation over the next several years but also signals that biotechs are confident about their futures.



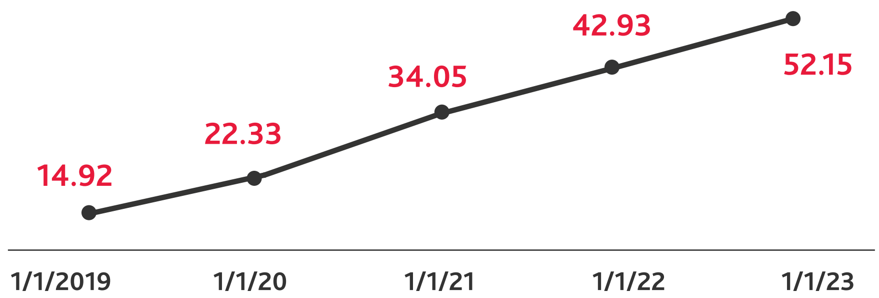




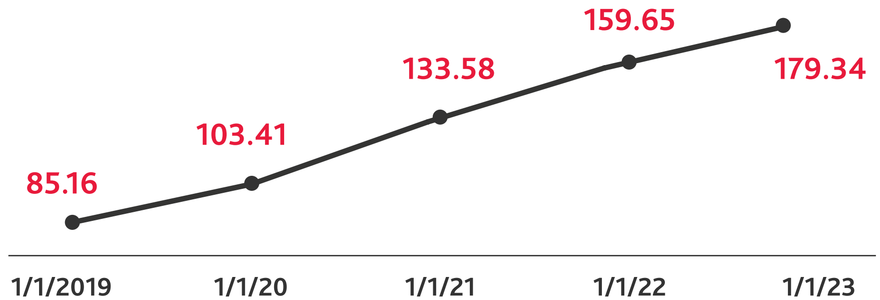


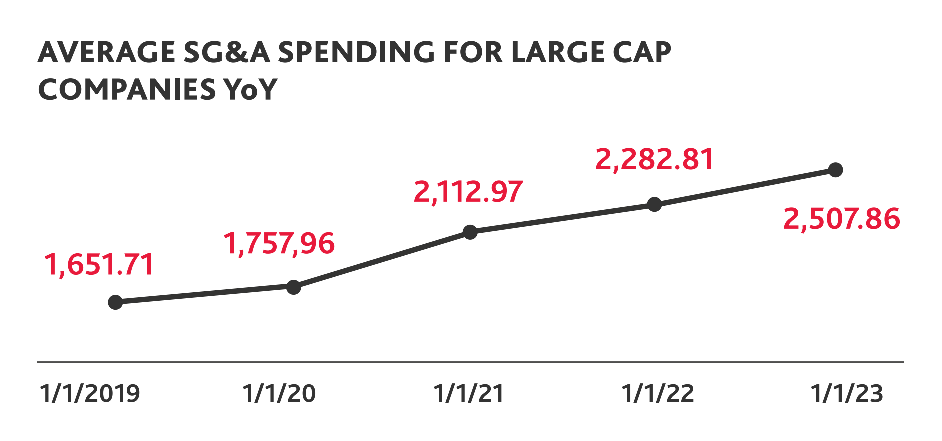
Medium-sized companies, on the other hand, saw a 1% decline in R&D spending. Given they increased their selling, general, and administrative (SG&A) budgets more than those of small and large companies, the decline in R&D spending could be a result of redirecting investment into their SG&A expenses. SG&A expenses have increased across the board of all company sizes. That said, some companies have had to invest in cost-cutting measures, like layoffs or focusing funds on further supporting existing successful products. This is particularly the case for biotechs that had drug candidates fail clinical trials and needed to redirect R&D budget to other areas before focusing on another project.

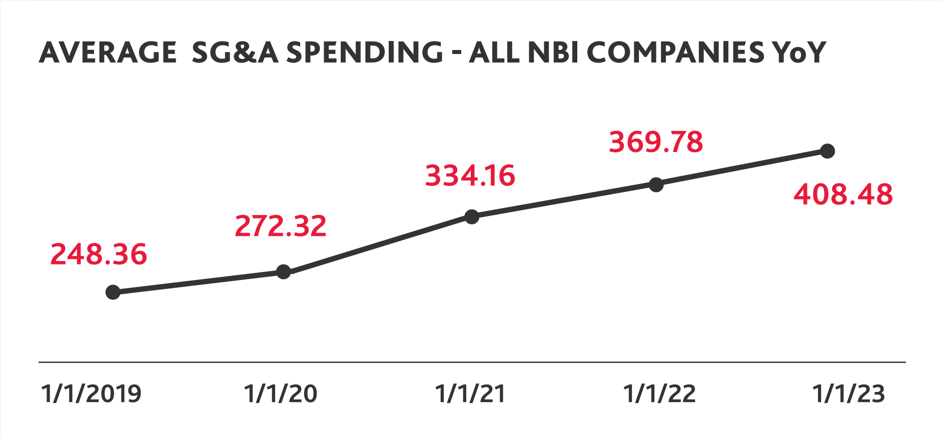
AVERAGE SG&A SPENDING FOR SMALL CAP COMPANIES YoY



AVERAGE SG&A SPENDING FOR MEDIUM CAP COMPANIES YoY







While medium-sized companies are pulling back on R&D spending, small biotechs have increased their R&D investments (34%). Small companies likely feel pressured to invest in R&D to advance drug candidates quickly and demonstrate sound clinical data to investors in today's difficult financing environment.

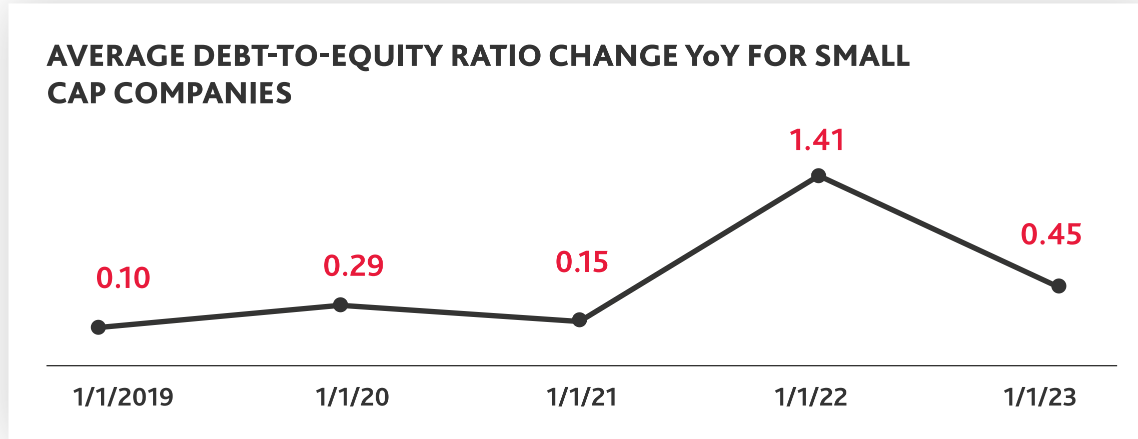
With the overall increase in R&D expenses, particularly for small companies which tend to be key engines of innovation for the industry, biotechs may see a rise in drug advancements, acquisitions, partnerships, and other activity in the year ahead. Based on BDO's experience, those developing drugs related to oncology, weight loss, and antibody-drug conjugates (ADC), have been notably successful throughout their financing rounds in the last year and could be prime contenders for collaborations and transactions. They will likely continue to drive licensing revenue, as valuable IP emerges from increased R&D efforts.

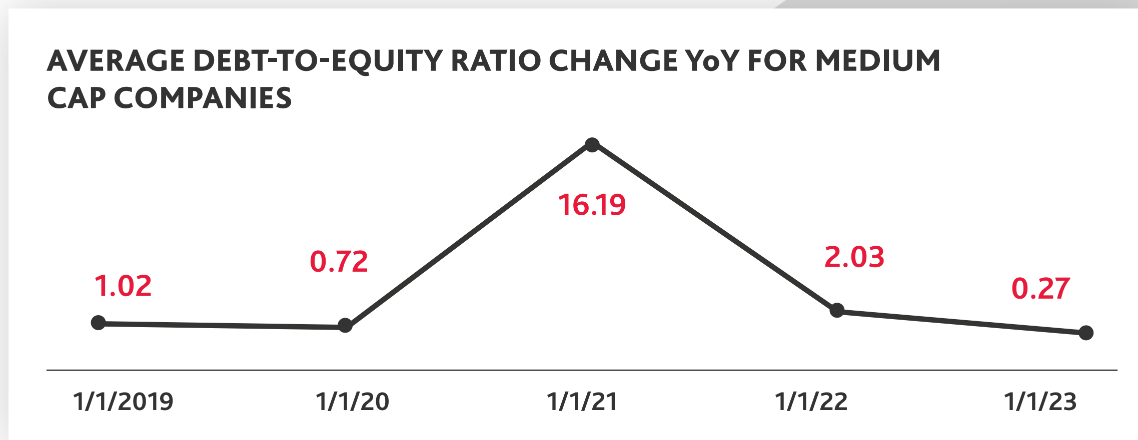
Financing the Future of Biotech

Raising capital could become a greater focus area for small cap companies given their increase in R&D spending and revenue declines in FY 2023. Many of the small companies that secured funds during the 2023 fiscal year, whether by issuing more equity, taking on debt, or going public, are likely to have immediately invested proceeds into R&D. An expected drop in interest rates might also stimulate the industry, prompting additional funding and potentially encouraging IPOs.

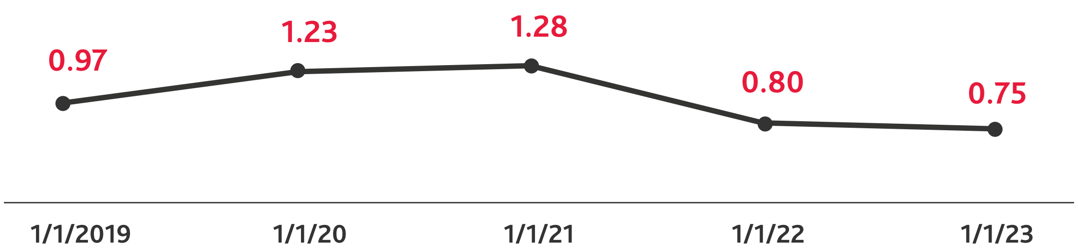
Another sign of future financial stability comes in the way of significantly smaller debt-to-equity ratios, particularly among small-sized companies. Sky-high interest rates have likely prompted smaller biotechs to pay off debt and issue more equity. Taking on debt remains prohibitively expensive for small biotechs and high interest rates have made it difficult for them to take on loans, making issuing equity the more attractive avenue to generate cash.

Unlike small-sized companies, large and medium biotechs saw only a marginal decline in their debt-to-equity ratio in FY 2023, likely due to issuing less equity to avoid diluting shareholders. Larger companies also deviated from their medium and small cap counterparts by taking on a significant amount of debt in FY 2023 – likely to lock in lower rates. Bigger biotechs are often seen as more reliable borrowers and may have been able to secure loans from banks that other companies were not.

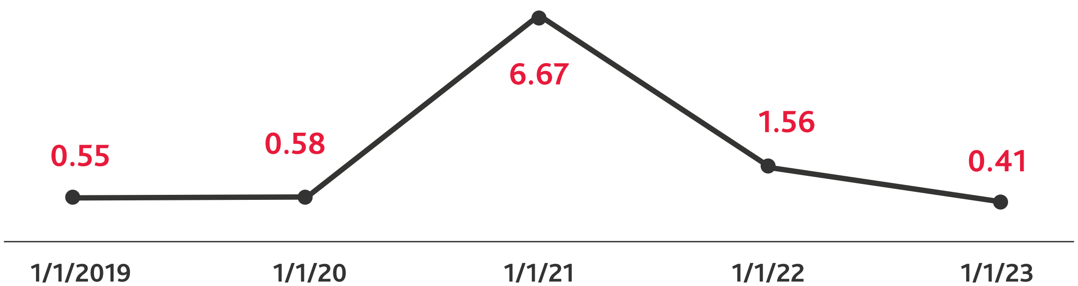


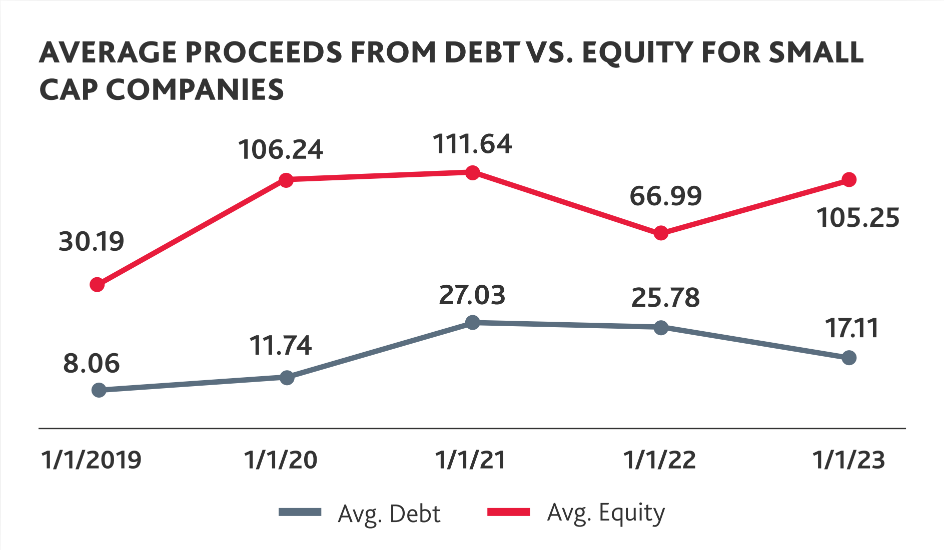


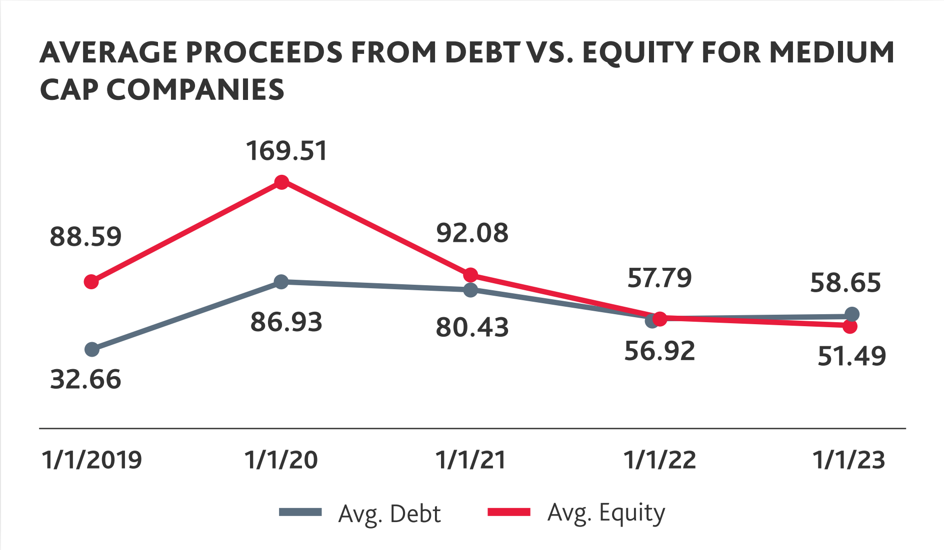
AVERAGE DEBT-TO-EQUITY RATIO CHANGE YoY FOR LARGE CAP COMPANIES

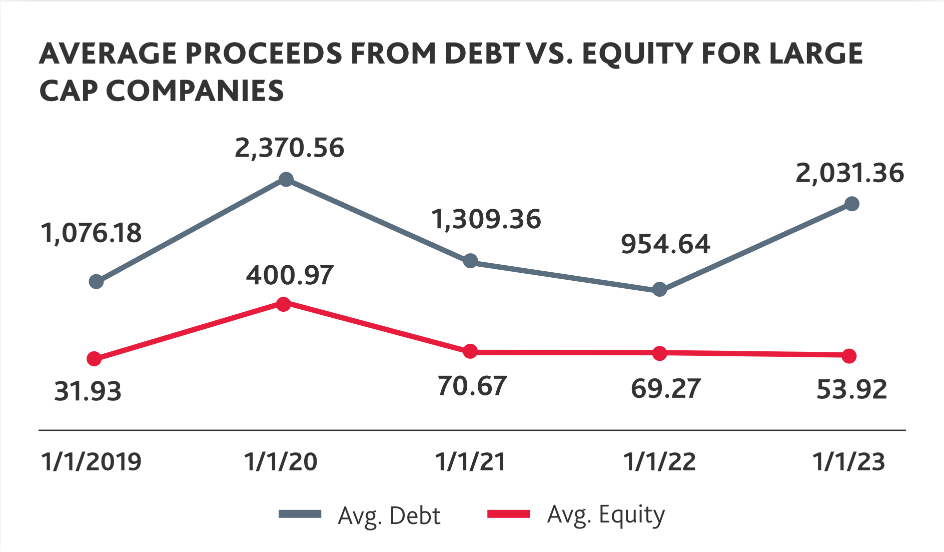


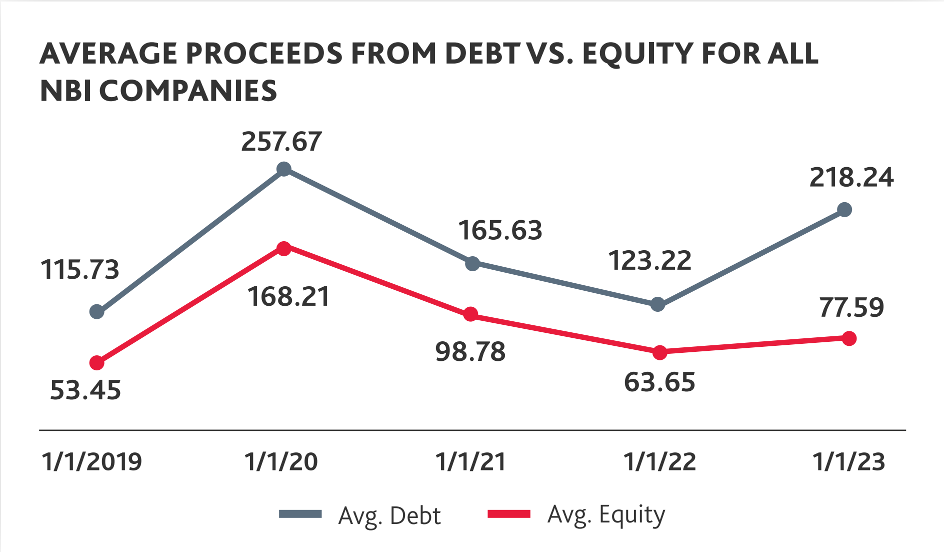
AVERAGE DEBT-TO-EQUITY RATIO CHANGE FOR ALL NBI COMPANIES YoY











Small companies will likely continue to funnel cash into R&D in the hopes of further developing their drug candidates to advance to clinical trials and attract licensing agreements, which can provide a source of revenue. While the biotech industry continues to see the number of licensing deals decline, the deals that were made yielded higher proceeds, according to JPMorgan's 2023 Annual Biopharma Licensing and Venture Report.

Looking Ahead

While biotechs continue to face financial obstacles, there are signs of renewing confidence in the industry.

Biotechs are adapting to a challenging economic climate by reducing their debt-to-equity ratios to insulate against high interest rates. The Federal Reserve has already cut interest rates by 50 basis points and is expected to further cut rates by the end of the year, which could spur additional investment in the industry. Additionally, a **recent rise in IPO activity** could mean the biotechs have more confidence in the industry, which could encourage further IPOs.

BDO has noted a rise in small and medium sized companies experiencing an influx of cash from licensing deals, which could signal increased confidence in the industry and its R&D developments. These companies, and particularly those in high-performing markets, will likely continue to see a boost in revenue due to licensing agreements. R&D investment is on the rise, positioning the industry to make impressive leaps in innovation. Even while revenue declined for some, biotechs continue to make substantial investments.

The industry has proven that it is ready and able to overcome challenges, so it can drive innovation and transform the future of biotechnology.

Want to learn more about how to manage your biotech's spending? Contact us. ▸

METHODOLOGY

The 2024 edition of BDO's Biotech Briefing analyzes the FY23 10-K filing data of companies listed on the Nasdaq Biotechnology Index, which includes organizations classified as biotech or pharmaceutical companies according to the Industry Classification Benchmark with a minimum market capitalization of at least $200 million and an average daily trading volume of at least 100,000 shares. BDO used CalcBench to conduct this data analysis and supplementary sources where noted. Numbers in all charts represent millions of U.S. dollars, except for debt-to-equity ratio.

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