BDO BIOTECH BRIEF | SUMMER 2021

REVENUE, R&D AND BIOTECH'S FUTURE

BDO

Contents

METHODOLOGY

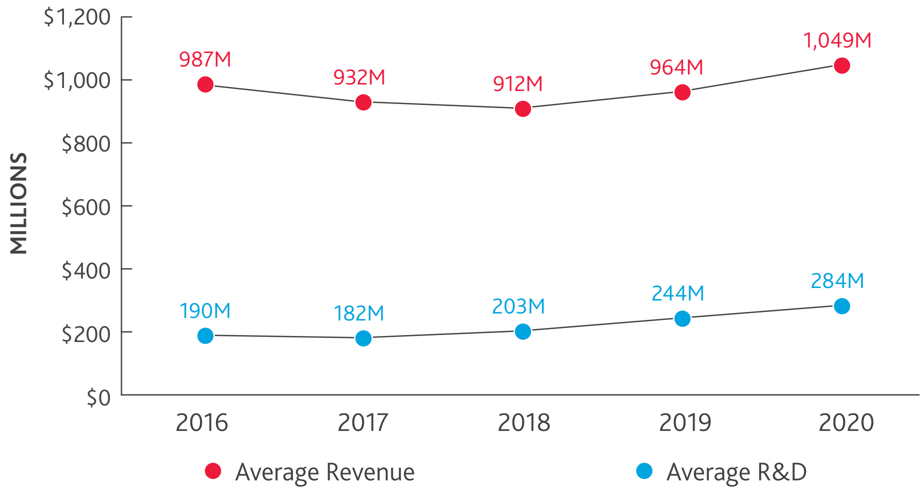
This edition of BDO's *Biotech Briefing* examines the most recent 10-K SEC filings of companies listed on the NASDAQ Biotechnology Index, which includes organizations classified as biotechnology or pharmaceutical companies according to the Industry Classification Benchmark that also have a market capitalization of at least $200 million. BDO used CapIQ and CalcBench to conduct this data analysis.

In September 2020, BDO's Biotech Brief found that R&D spending was outpacing revenue. But in 2021, that trend has started to reverse for medium and large companies, although small companies still spend significantly more on R&D compared to revenue. What is behind this increase in revenue and what are biotechs planning to do with the cash?

THE REVENUE AND R&D RELATIONSHIP

Companies listed on the NASDAQ Biotechnology Index (NBI) saw a 9% growth in average revenue to $1.049 billion in 2020 from $964.42 million in 2019. Average R&D spend increased by 16% in 2020 to $284.25 million from $244.34 million in 2019. However, the pace of growth in R&D spending is slowing as 2019 saw a 20% increase over 2018. While R&D spending has not decreased, is the slower pace a reflection of COVID's impact to starting new clinical trials? Should we expect a rebound in R&D post-COVID?

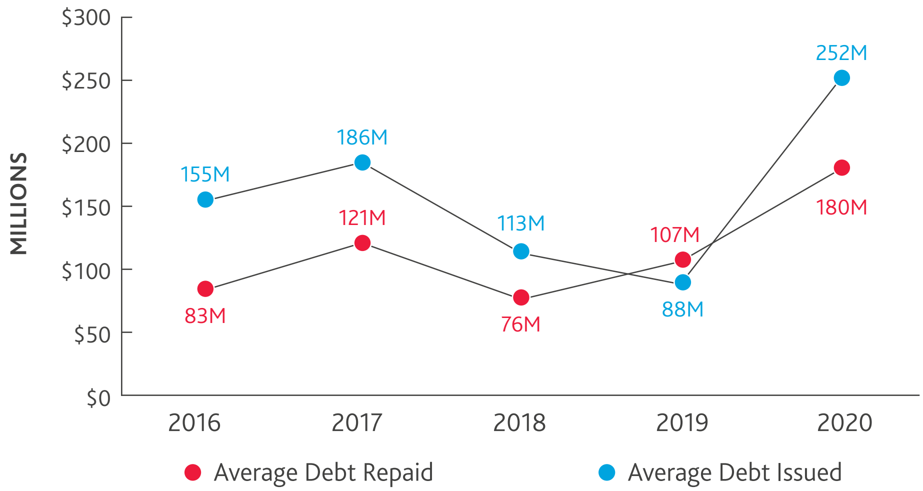
AVERAGE REVENUE VS R&D – ALL NBI COMPANIES



MORE DEBT COULD LEAD TO MORE M&A

On top of that, biotech companies took on significantly more debt in 2020 compared to 2019, with a 185% increase year-over-year. This could be due to needing cash to fund COVID-19 research, low interest rates or the low cost of capital. Issued debt means biotech companies now have more cash on hand—could this mean an M&A resurgence?

AVERAGE DEBT REPAID VS DEBT ISSUED – ALL NBI COMPANIES



REVENUE OUTPACES R&D SPEND

While biotech revenue is starting to outpace R&D spend overall, the picture also looks different for small, medium and large companies.

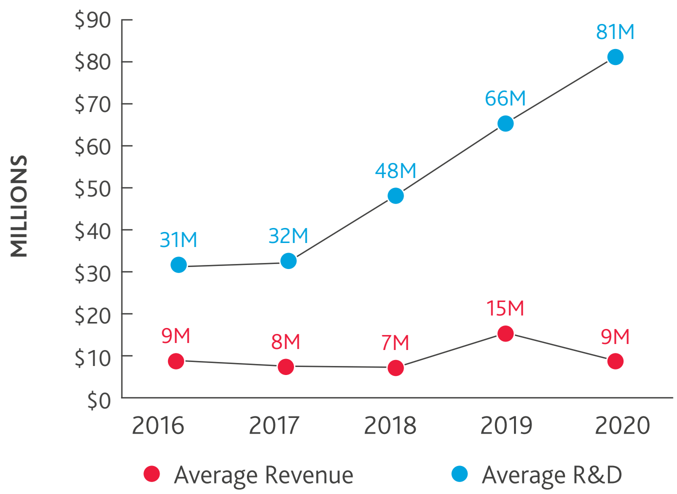
REVENUE

	Small-cap	Mid-cap	Large-cap
Revenue Change (2019-2020)	-41.63%	+30.26%	+7.5%
Revenue Change (2018-2019)	+112.5%	+18.61%	+4.09%
Revenue 2020	$9.03 million	$257.01 million	$8.192 billion
Revenue 2019	$15.47 million	$197.30 million	$7.62 billion
Revenue 2018	$7.28 million	$166.35 million	$7.32 billion

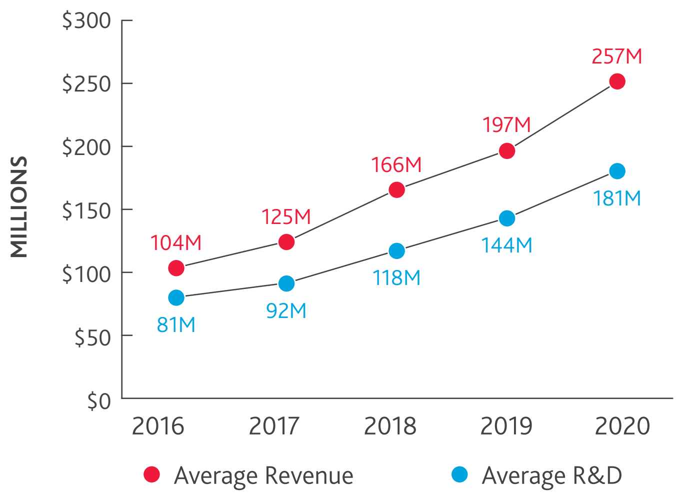
R&D

	Small-cap	Mid-cap	Large-cap
R&D Spend Change (2019-2020)	+24.19%	+26.13%	+11.34%
R&D Spend Change (2018-2019)	+35.62%	+21.99%	+16.76%
R&D Spend 2020	$81.46 million	$181.22 million	$1.512 billion
R&D Spend 2019	$65.59 million	$143.67 million	$1.358 billion
R&D Spend 2018	$48.36 million	117.77 million	$1.163 billion

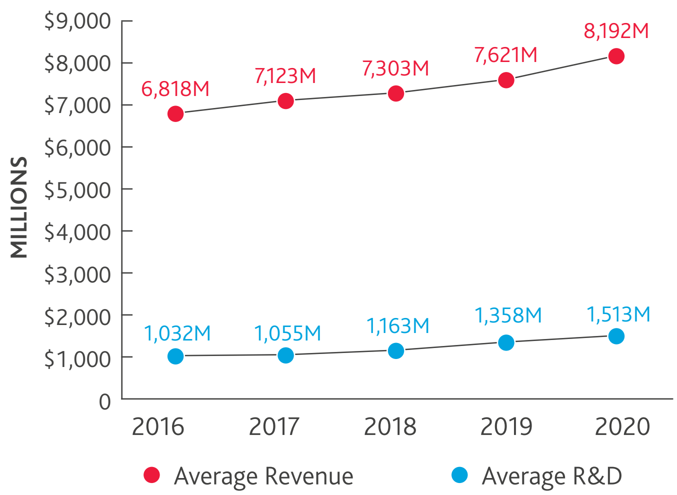
AVERAGE REVENUE VS R&D – SMALL COMPANIES



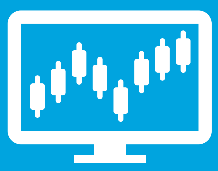
AVERAGE REVENUE VS R&D – MEDIUM COMPANIES



AVERAGE REVENUE VS R&D – LARGE COMPANIES



The disproportionate spend on R&D compared to revenue by small companies is to be expected, as smaller companies tend to spend much more on R&D to get products to clinical stage trials and to market.



A RECORD **84** companies were added to the NASDAQ Biotech Index in 2020

87% Of biotech IPOs in 2020 were small cap companies

The drop in revenue from smaller companies is likely due to more companies being added to the NASDAQ Biotech Index who are pre-revenue but have achieved the market cap needed to make the index.

IS THE R&D SPENDING SLOWDOWN TEMPORARY? CAN WE EXPECT A REBOUND POST-COVID?

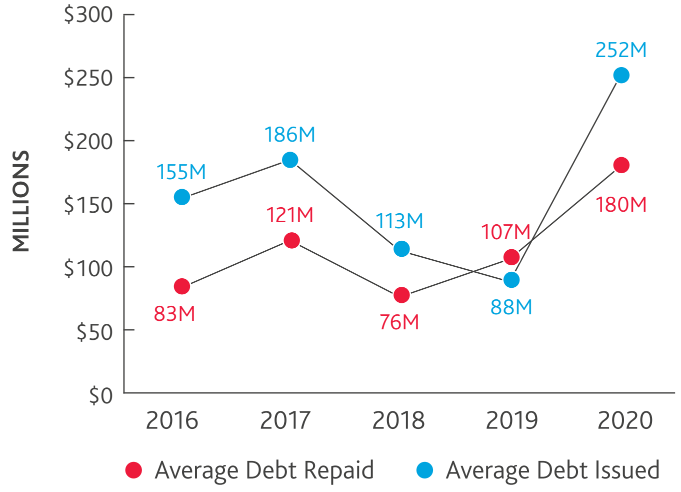
In March 2021, Senate Democrats introduced new legislation to cap drug pricing. While it is still too early to tell if this legislation will pass Congress or exactly what the effects will be, this news did cause biotech stocks to drop in early April. The industry is concerned that pricing caps could cause investors to press pause on investment, which in turn could constrict the drug pipeline and result in decreased R&D spending. A cap on pricing could discourage companies from continuing to research new treatments and cures for complex diseases, such as Alzheimer's, and instead focus on generics and currently produced drugs.

Finally, supply chain disruptions and shortages, as well as disruptions of clinical trials due to COVID-19, could be one reason R&D spending did not increase as fast as it has in years past. Companies faced issues when it came to getting raw materials and operating facilities at full capacity due to COVID-19 restrictions. However, many life science CFOs have high expectations for R&D in 2021, as 69% plan to increase investment into R&D, according to BDO's 2021 Life Sciences CFO Outlook Survey.

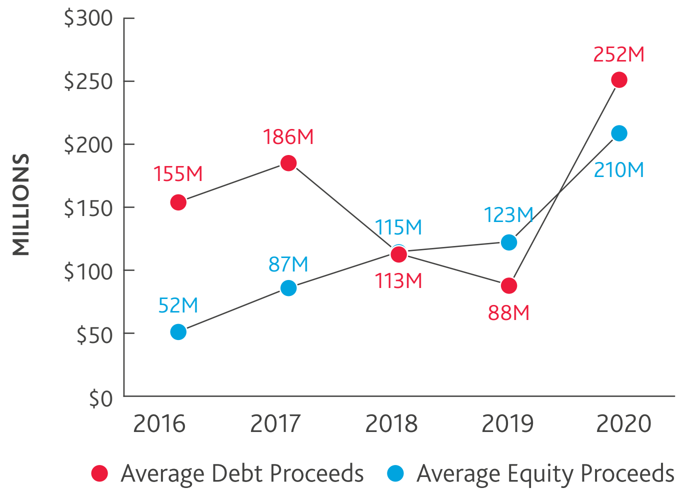
DEBT AND EQUITY PROCEEDS SPIKED IN 2020

The onset of the pandemic, coupled with historically low interest rates, gave biotechs the opportunity to secure low-cost funding to ride out clinical delays and potentially position themselves for longer-term R&D or M&A activity. But as the markets for biotech stocks spiked in 2020, biotechs raised a significant amount of capital through equity, while continuing to borrow. In 2020, biotechs issued 185% more debt than in 2019 and debt issued surpassed debt repaid. Many of these companies plan to use proceeds to repay existing debt, as debt repaid increased 69% from 2019, and for selling, general and administrative expenses (SGA).

AVERAGE DEBT REPAID VS DEBT ISSUED – ALL NBI COMPANIES



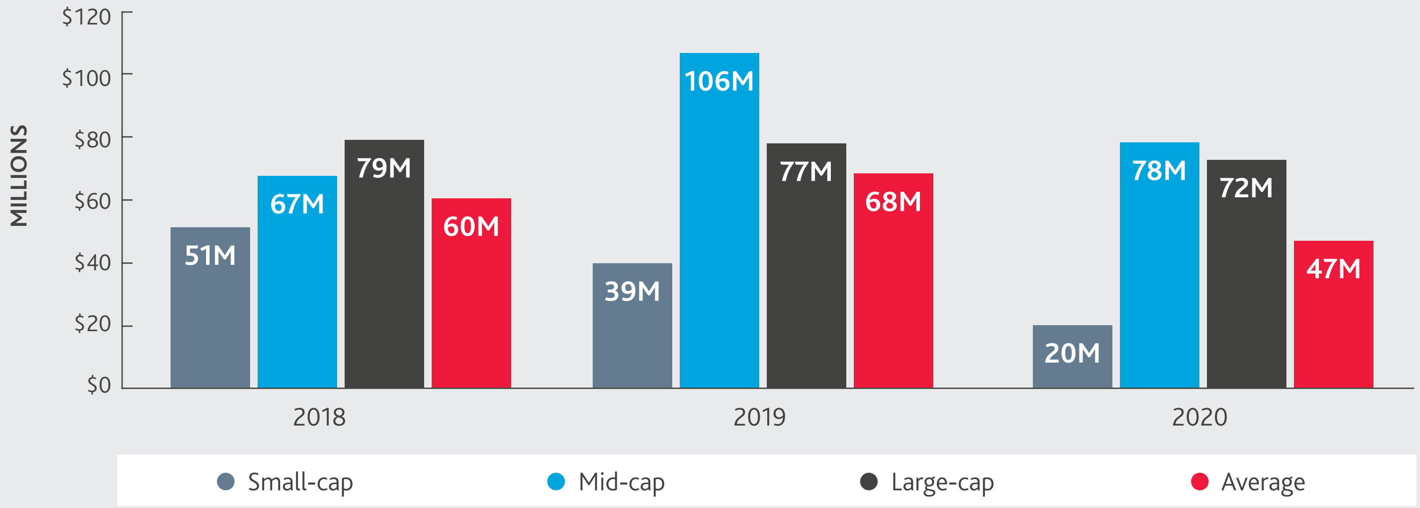
AVERAGE PROCEEDS FROM DEBT VS EQUITY – ALL NBI COMPANIES



The high amount of issued debt gave a boost to cash on balance sheets and proceeds from debt now surpass proceeds from equity. However, 2020 was also a record high for equity proceeds, due to a record-breaking year for the NBI and a biotech IPO boom. With the money raised, biotechs can continue to fund R&D for complex drugs and consider M&A transactions.

As the economy returns to normal, interest rates are unlikely to fall any further and biotechs may not be able to continue to rely on easily available cash in the form of debt. Companies will also need to ensure their debt-to-equity ratio does not put them in an unnecessarily risky position. Despite debt proceeds surpassing equity proceeds, the debt-to-equity ratio decreased, as biotechs saw a stock market and IPO boom in 2020.

DEBT-TO-EQUITY RATIO



MORE CASH ON BALANCE SHEETS COULD LEAD TO MORE M&A, FOLLOWING A 2020 SLOWDOWN

With all this cash on balance sheets, coupled with a potential slowdown of R&D spending, we may start to see an M&A resurgence, following a slowdown during the pandemic.

The annual American Society of Clinical Oncology meeting was held this year from June 4-June 8 and presented an opportunity for large and small drugmakers to present clinical trial research for cancer treatments. Amgen presented findings on Lumakras, a drug that recently received FDA approval to treat metastatic non-small cell lung cancer, while Hillstream Biopharma announced the progress of HSB-1216, a novel-inducer of iron-mediated cell death, used to treat triple-negative breast cancer. These developments and other research presented at the conference spurred a 5% increase in the NASDAQ Biotech Index between June 4 and June 8. As the conference traditionally presents an opportunity to shop for acquisitions, we may see more acquisitions in the coming months, especially as cancer drugs remain highly profitable.

One potential wrench in this expected deal-making surge is that the Federal Trade Commission (FTC) is forming a multilateral working group to reassess their approach to approving pharmaceutical deals. Increased scrutiny into transactions will likely make it more difficult for deals to get approved, but it remains too early to tell what the working group's outcome will be.

Another consideration is that, with company valuations being so high, finding a target can get quite expensive. Larger pharma companies are likely to continue to look at earlier stage targets for co-development or acquisitions.

BIOTECH AT A CROSSROADS

It's an interesting time for biotech companies. As the pandemic wanes, R&D priorities may start to shift due to medical and technical advancements. New legislation could impact business models, and a flush of cash also means the industry is ripe for deal making and innovation.

For biotech leaders, it's important to conduct proper scrutiny when pursuing an acquisition. If the goal is to make your company attractive to a buyer, you need to ensure your company's financial health is in good shape and potentially optimize costs and speed products to market. And while debt financing can be useful in gathering enough cash to achieve business goals, it's crucial not to take on too much risk.

CONTACTS

Considering M&A, need guidance on R&D and revenue, or looking to optimize costs, manage risks or improve speed to market? Don't do it alone—reach out for the right resources and guidance.

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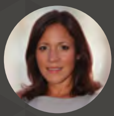

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