

Contents

- **03** BIOTECH IN 2022: KEY FINDINGS
- REVENUE INCREASED SHARPLY IN 2021 & PROFITS ARE UP ON AVERAGE
- **07** VALUATION GAINS FROM 2020 HAVE BEEN ERASED
- R&D SPENDING CONTINUES TO INCREASE, BUT SLOWS FROM 2020
- DEBT AND EQUITY ISSUED NOW WILL PROVIDE A CUSHION IN A COOLING MARKET
- 11 IMPLICATIONS OF CASH AND DEBT ON DEAL MAKING
- 13 MANUFACTURING CAPACITY BIOTRAK® DATA
- 15 BIOTECH REGIONAL HUBS
- 18 WHAT'S AHEAD FOR BIOTECH
- 20 CONTACT

METHODOLOGY

This edition of BDO's Biotech Brief 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 CalcBench to conduct this data analysis.

This report defines large companies as those with over \$1 billion in revenue. Medium companies have between \$50 million and \$1 billion in revenue and small companies have under \$50 million in revenue. All chart data is in millions of U.S. dollars.

Key findings

Each year, BDO analyzes the most recent 10-K SEC filings of companies listed on the NASDAQ Biotechnology Index (NBI) to uncover important trends in the biotech industry. Our most recent analysis shows that the break-neck pace of 2020 is over, but the biotech industry remains resilient.



Stock prices have decreased, but revenue growth is impressive, which could help biotechs stay steady in a cooling economy.



While R&D investment

is still on the rise, it's starting to slow, it remains to be seen whether strong profits will be invested back

into R&D.



Even in a recession, groundbreaking medicine will continue to be funded, but **investors and large pharmaceuticals will be looking at products with a critical lens,** becoming more selective with their cash and investments.



Biotechs are seeing fewer proceeds from both debt and equity compared to 2020,

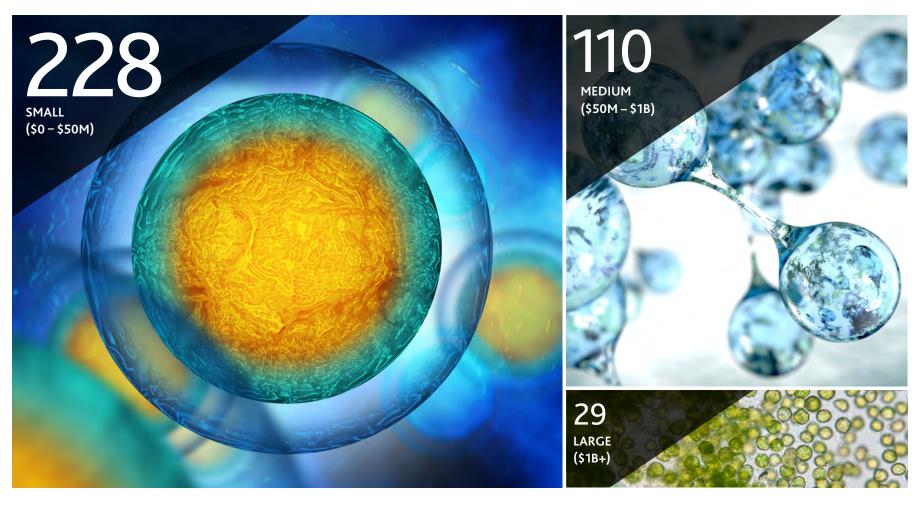
and small- and medium-sized biotechs have less cash on hand. Biotechs and investors alike will be taking a close look at their pipeline development strategy and may turn to acquisitions for support.



ABOUT THE NBI

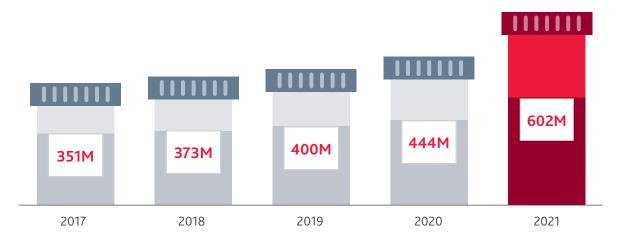
The NBI contains securities of NASDAQ-listed companies classified according to the Industry Classification Benchmark as either biotechnology or pharmaceuticals. The NASDAQ Biotechnology Index is calculated under a modified capitalization-weighted methodology. As of December, 2021, there are 367 companies on the NBI.

Here is the distribution of small, medium and large companies on the index:



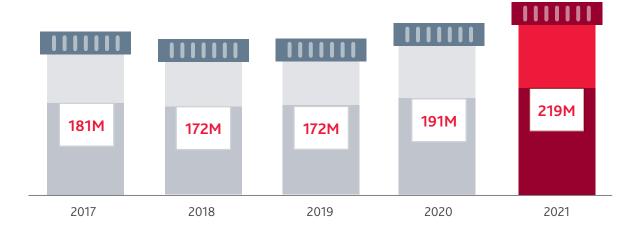
For the purposes of this report, we are defining small, medium and large biotechs as: **Small:** \$0-\$50 million in revenue. **Medium:** \$50 million-\$1 billion in revenue. **Large:** \$1 billion+ revenue All chart data is in millions of U.S. dollars and all charts refer to companies on the NBI.

AVERAGE TOTAL OPERATING PROFIT



With profits up dramatically, biotech companies are pushing more of their cash to selling, general and administrative expenses (SG&A). The SG&A spending could help biotechs boost revenue for their current product offerings.

AVERAGE TOTAL SG&A SPENDING





Valuation gains from 2020 have been erased

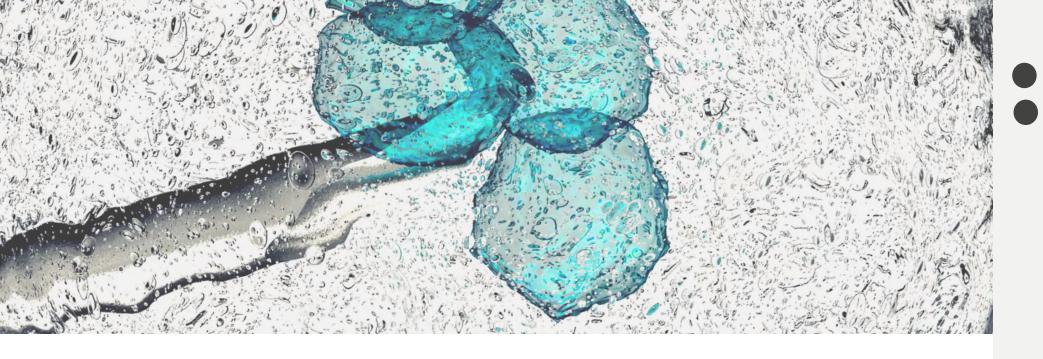
While the average valuation of biotechs on the **NBI increased** by 24% in 2020, valuations declined by 24% in 2021. The rally of 2020 is over as the stock market enters bear territory.

AVERAGE YEAR END STOCK PRICE



Additionally, repurchase of the common stock declined by 29% on average. Biotechs have come under criticism for buying back stock instead of investing in R&D, and this criticism was more pronounced during COVID-19. With high valuations for the first half of 2021, biotechs may not have seen the value in buying back their own stock. However, in 2022, **BioNTech** announced plans to do the same, to help bolster valuations. Available cash reserves may allow for more buybacks in 2022. However, shareholders and investors would likely rather see investments in R&D, acquisitions or partnership agreements to grow pipelines, rather than pursuing stock buybacks.



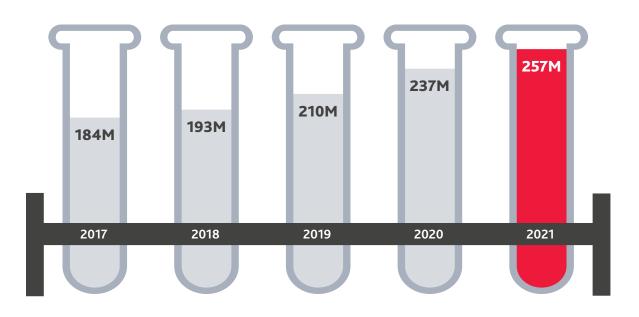


R&D spending continues to increase, but slows from 2020

Biotechs continued to **spend** heavily on **R&D** in 2021

The year's long trend of increasing R&D spending has paid off in the form of a revenue spike. But there is evidence the pace of R&D spending is starting to slow. R&D spending increased by 9% in 2021, compared to 13% in 2020, the largest increase in spending in the past five years.

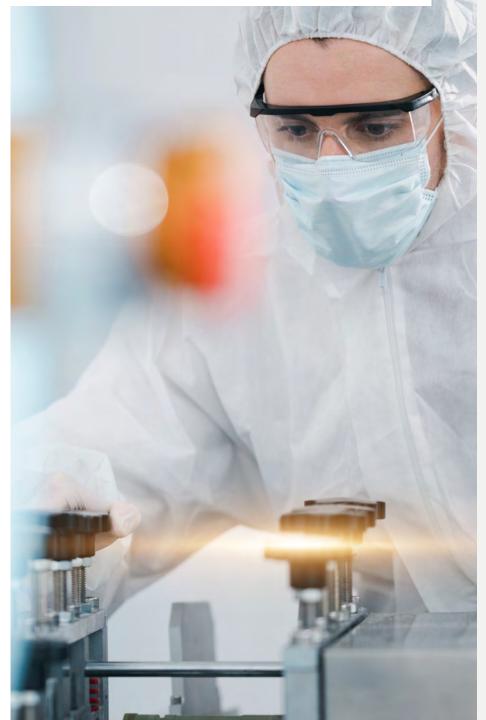
AVERAGE TOTAL R&D SPENDING



With low interest rates, biotechs loaded up on debt in 2020. But by 2021 proceeds from the issuance of debt decreased by 36% in 2021, down from a 174% increase in 2020.

AVG PROCEEDS FROM DEBT VS EQUITY - ALL NBI COMPANIES



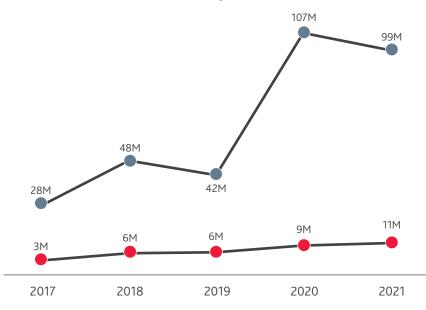


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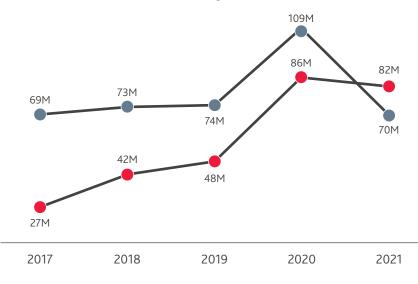


While interest rates remained low in 2021, biotechs were not in need of additional cash. Additionally, the anticipation that interest rates would soon rise likely led to less issuance of debt, compared to previous years.

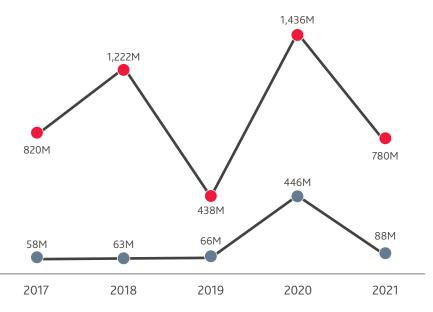
AVG PROCEEDS FROM DEBT VS EQUITY - SMALL COMPANIES



AVG PROCEEDS FROM DEBT VS EQUITY - MEDIUM COMPANIES



AVG PROCEEDS FROM DEBT VS EQUITY - LARGE COMPANIES



The debt that biotechs have taken on now will help provide cash as interest rates rise and funding from investors dries up. The relationship between debt/equity and R&D is one to watch. Smaller biotechs primarily finance R&D and clinical trials through equity, while larger companies primarily finance through debt, so as not to dilute shares.

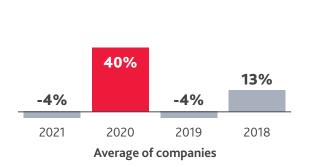
A dip in equity could shrink the research and clinical trial budgets of small companies, forcing them to make hard decisions on which clinical trials to fund. Shrinking equity could push biotechs to look to partnerships or M&A as a source of investment. The decline in valuations and tightening of cash means big pharma is likely on the hunt for bargain buys.

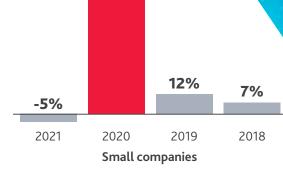
Average Debt Proceeds

Average Equity Proceeds

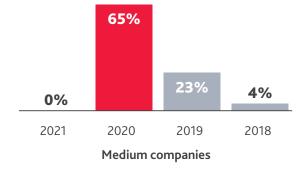
On average, cash and equivalents have decreased slightly, following a strong increase in 2020. Small companies saw cash and equivalents decrease while medium and large companies saw slight increases.

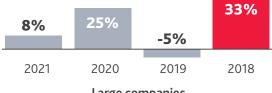
YOY CHANGE IN CASH AND EQUIVALENTS





102%

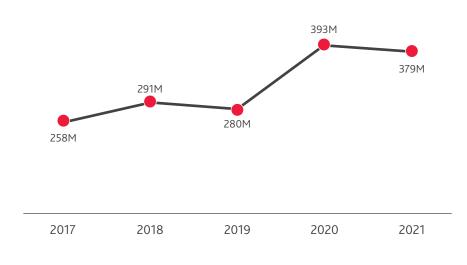


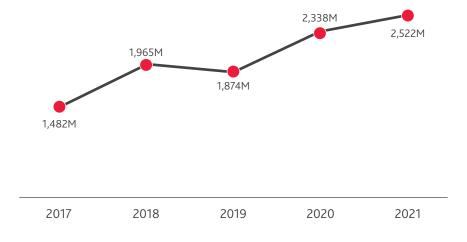




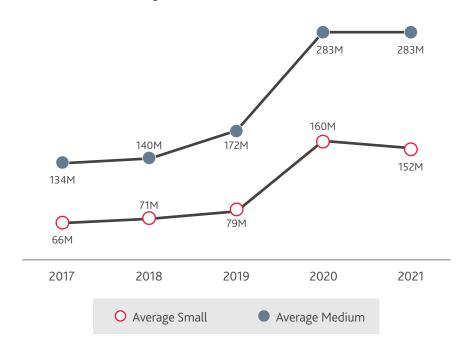
AVERAGE CASH & EQUIVALENTS - ALL COMPANIES

AVERAGE CASH & EQUIVALENTS - LARGE COMPANIES





AVERAGE CASH & EQUIVALENTS - SMALL & MEDIUM COMPANIES



Companies that saw the largest increase in cash include Moderna and BeiGene. While much of Moderna's cash came from sales of its COVID-19 vaccines, BeiGene's cash increased by almost \$3 billion due to its IPO on the Science and Technology Innovation Board (STAR Market) of the Shanghai Stock Exchange (SSE).

Large companies are faring well on cash, and while cash increases and debt proceeds did not increase as dramatically as they did in 2020, large companies are in the right position to make strategic investments to bolster their pipelines. If small companies can demonstrate that they have a promising product but need the cash and expertise in bringing it to commercialization, they'll be attractive investments. We expect to see more deals, including acquisitions and collaboration agreements, as well as companies selling off assets that are outside of their core area of focus if in need of cash.

Manufacturing capacity – bioTRAK® data

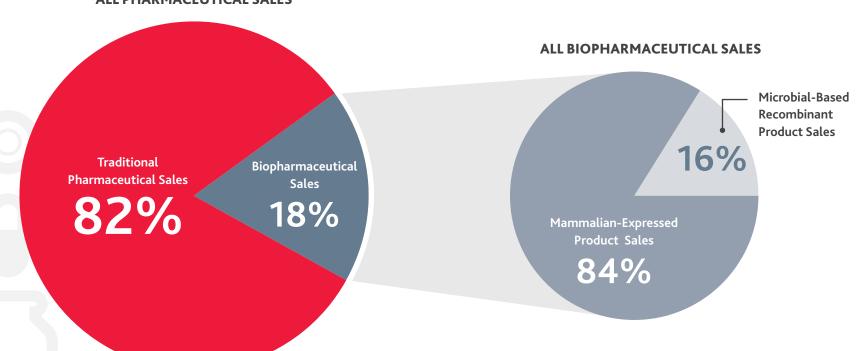
The biopharmaceutical industry is growing and shows no signs of slowing.

According to BDO's bioTRAK® database, which tracks the demand and supply of biomanufacturing capacity, **biopharmaceutical sales have grown 60% in the last** five years, whereas traditional pharmaceutical sales have grown 22%.

Currently, biopharmaceutical sales represent 18% of the global pharmaceutical market. Primarily composed of two expression systems, mammalian and microbial, few biopharmaceuticals are manufactured in other expression systems (i.e., insect or plant cell culture).

As biopharmaceuticals continue to be discovered, developed and commercialized, the biopharmaceutical market continues to grow and we're seeing supply and demand expand rapidly.

ALL PHARMACEUTICAL SALES



DEMAND CONTINUES TO GROW*

With an increasing pipeline of products expected to be commercialized by 2026, along with over 300 currently marketed biopharmaceuticals, demand for recombinant products (measured in kg) is projected to significantly increase for both mammalian and microbial-expressed recombinant products:

Product Expression	Projected Kilogram Demand Increase	Projected Annual Growth Per Year (L)
Mammalian	>100%	9.8%
Microbial (Excluding Insulin)	~90%	11.2%

SUPPLY GROWTH PROJECTED AT 3-6%*

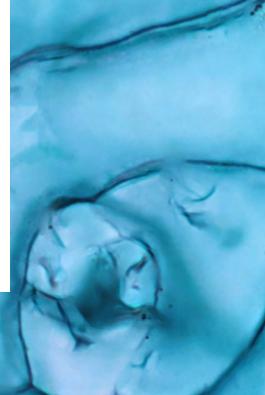
The supply of both recombinant mammalian and microbial capacity is projected to increase significantly over the next five years, with mammalian capacity growing twice as fast:

Product Expression	Capacity 2022	Projected Capacity by 2026	Percent Increase	Annual Growth Rate Per Year Since 2022
Mammalian	6.1 ML	7.6 ML	24%	5.6%
Microbial (Excluding Insulin)	0.53 ML	0.60 ML	12%	2.9%

Most mammalian capacity (nearly 40%) is currently located in North America; however, by 2026, Europe's capacity is projected to surpass North America's due to significant planned expansions.

By contrast, most recombinant microbial capacity (60%) is currently located in Europe. North America is projected to increase capacity slightly by 2026 (from 31% to 35%) and Europe's capacity is expected to decrease to 56% by 2026.

WANT FULL ACCESS TO BDO'S BIOTRAK® DATABASE INSIGHTS? Reach out to <u>Dawn Ecker</u> for more information.



^{*} Product sales, kg and volumetric demand for recombinant therapeutics specifically designed to treat SAR-CoV-2 infection (COVID-19) are not included within this dataset at this time. These recombinant therapeutics currently have a unique demand profile resulting in unique assumptions and require a modified forecast methodology.

Biotech regional hubs

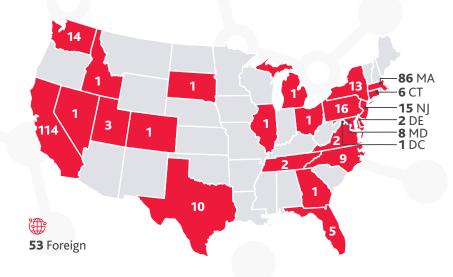


The biotechnology industry has long been concentrated in California and Massachusetts, with smaller hubs in select states on the West Coast and Northeast, such as New Jersey, Pennsylvania, New York and Washington. However, we are seeing biotech hubs emerge and expand in the south and southeast region in Texas, North Carolina and Maryland.

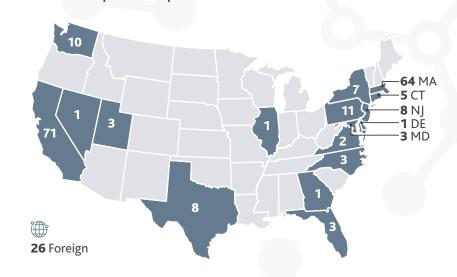


Number of biotechs on the NBI by state headquarters

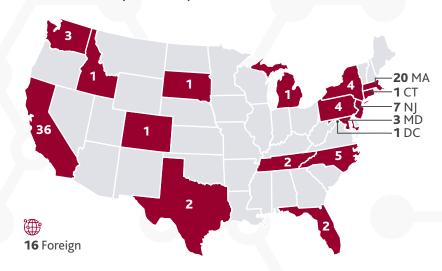
ALL COMPANIES | Total 367



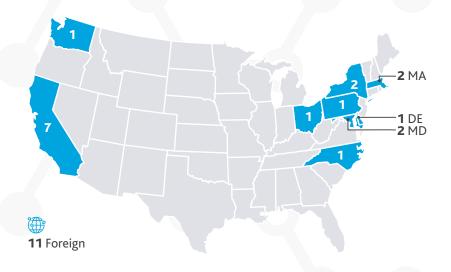
Small Companies | Total 228



Medium Companies | Total 110



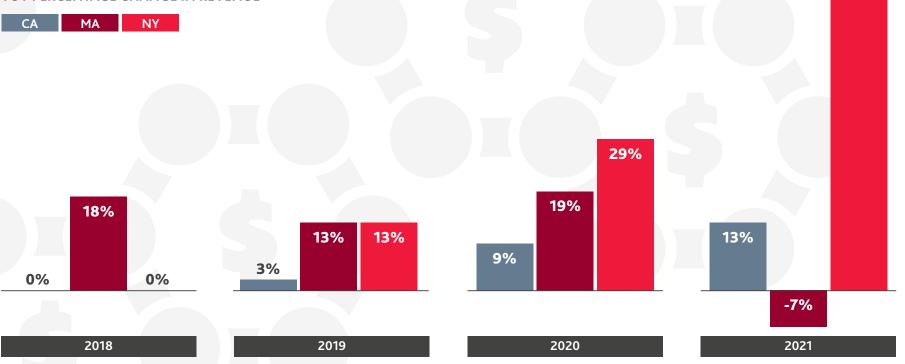
Large Companies | Total 29



While California has the most NBI biotech companies at 114, **New York biotechs have seen impressive revenue growth since 2019**, while companies in Massachusetts and California experienced slower growth or even declines. The growth of New York companies is shared by companies in the state and is not due to one particular outlier.

73%

YOY PERCENTAGE CHANGE IN REVENUE







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