

A close-up photograph of a female scientist with brown hair, wearing clear safety goggles and a white lab coat. She is looking down intently at her work. In the background, another person in a lab coat is visible, and various pieces of laboratory glassware, including a round-bottom flask containing a blue liquid and several test tubes, are in focus. The lighting is bright and clinical, typical of a laboratory setting. A red vertical bar is visible on the left side of the image.

# 2015 BDO BIOTECH BRIEFING



“Optimism surrounding the opportunities for further drug development in light of a continued increase in the approval of new drugs by the FDA supports investment in R&D. However, political controversy and widespread criticism around rising drug prices have made investors skittish, and we have seen that recently reflected in valuations.”

Ryan Starkes, partner and leader of the Life Sciences Practice at BDO.



# Biotech Fever Drives Boom in R&D Spending

While biotechs have been booming for the past few years, and started 2015 on good footing, the events of the last few months have resulted in significant volatility and erosion of value. According to the Financial Times, U.S. pharmaceutical and biotech stocks have lost more than \$40 billion in value since the recent drug pricing firestorm broke out. Such volatility is expected to persist, at least in the short run.

However, many of the positive trends that drove the industry to new heights in 2014 have carried over into 2015, and are expected to continue. Novel new drug approvals hit an 18-year high in 2014, with a total of 41 New Molecular Entities (NMEs) receiving FDA approval. 2015 has continued the high pace of drug approvals, with 29 NMEs approved as of October.

Signaling future growth, the 2015 BDO Biotech Briefing found that average R&D expenditures increased 18 percent in 2014, reaching \$55.6 million, up from \$47.1 million in 2013 and \$40.7 million in 2012. Even as biotech stocks temporarily falter, R&D spend is anticipated to continue to increase in the year ahead.

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The BDO Biotech Briefing examined the most recent 10-K SEC filings of companies listed on the [NASDAQ Biotechnology Index](#). Companies reporting more than \$300 million in revenue were excluded to ensure findings are representative of the vast majority of companies included in the NASDAQ Index. Remaining companies were divided into two groups—those with more than \$50 million in revenue and those with less than \$50 million in revenue—to identify trends and key metrics relevant to each group. The average market cap of companies in the study as of the end of their most recent fiscal year is \$1.14 billion.

## ABOUT THE TECHNOLOGY & LIFE SCIENCES PRACTICE AT BDO USA, LLP

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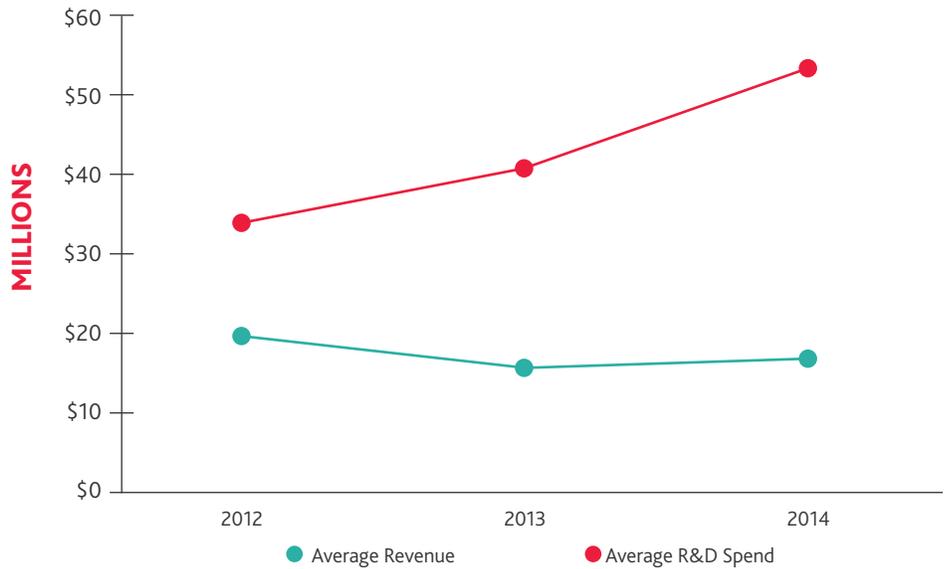
## With Soaring Revenues, R&D Budgets Continue to Climb

Small biotechs--companies with less than \$50 million revenue--saw the biggest hike in R&D spending, reporting an increase of 28 percent to \$52.6 million, compared to a 20 percent growth rate in 2013. Part and parcel with this surge in spending, average R&D expenditure as a percentage of revenue among smaller biotechs leapt to 313 percent, up from 261 percent in 2013, clearly highlighting that R&D spending decisions at such companies are not based on the top line revenues.

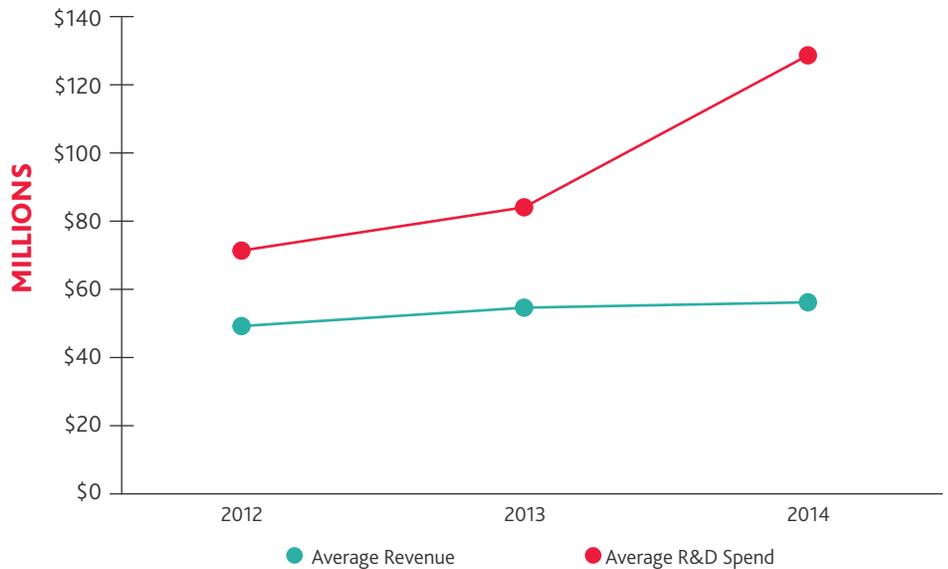
Large biotechs increased R&D spending by seven percent in 2014 to \$58.1 million, down from 10 percent the prior year. Average R&D expenditure as a percentage of revenue actually decreased to 83 percent, down from 101 percent in 2013. However, this decrease is not an indicator of industry caution, but the result of the significant leap in revenues generated by larger biotechs across the industry.

Revenue among all biotechs on the index jumped 44 percent in 2014 to \$67.1 million, up from a seven percent growth rate in 2013. Large biotechs led the acceleration in growth, increasing their revenues by 52 percent to \$129.3 million, compared to 17 percent the previous year. Small biotechs reported more modest revenue growth at seven percent, up from a decrease of 21 percent seen over the prior year. Approximately three-quarters (78 percent) of all companies analyzed reported losses in 2014.

### R&D SPEND AND REVENUE TRENDS FOR SMALL BIOTECHS



### R&D SPEND AND REVENUE TRENDS FOR LARGE BIOTECHS



**Small biotechs** — companies on the NASDAQ Biotechnology Index with revenues below \$50 million

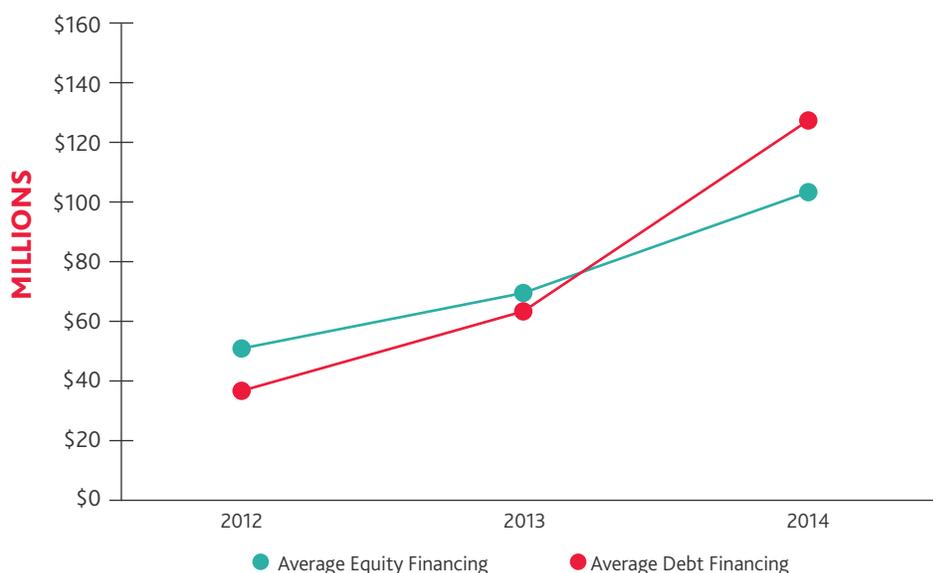
**Large biotechs** — companies on the NASDAQ Biotechnology Index with revenues greater than \$50 million

## Debt Financing Doubles

While the bulk of biotechs secured financing through the equity markets, those who sought debt financing raised much larger amounts. Seventy-one percent of biotechs secured equity financing, whereas only 34 percent of companies secured financing through the credit markets. Companies seeking debt financing raised an average of \$128.6 million, nearly double (97 percent more) the average size of 2013 financings. Large biotechs secured more than twice the average amount of debt financing than small biotechs, raising an average of \$170.3 million. Forty-three percent of large biotechs sought debt financing, up seven percentage points from 2013. By comparison, only 27 percent of small biotechs secured financing through the credit markets, down from 31 percent the prior year.

Companies seeking equity financing secured an average of \$104.5 million, up 32 percent from 2013, with little distinction between large and small biotechs of the average amount raised. However, a substantially higher percentage of small biotechs pursued equity financing (83 percent) as compared to larger biotechs (57 percent).

## FINANCING ACROSS BIOTECHS



## Biotech Goes on a Hiring Spree

Biotechs went on a hiring spree in 2014, reporting an average of 216 employees, 21 percent higher than 2013 levels. Among larger biotechs, average headcount moved from 278 to 345, an increase of 24 percent. Small biotechs saw more moderate but still significant growth, increasing average headcount by 14 percent to 105 employees.

With industry-wide growth and increased demand for top R&D talent, competition for candidates is intensifying. BDO's third annual [Life Sciences RiskFactor Report](#) found that 91 percent of life sciences companies cite their ability to attract and retain talent as a critical risk to their business. The outlook for 2016 is less clear, however, as a few recent setbacks have dampened hiring prospects for some.

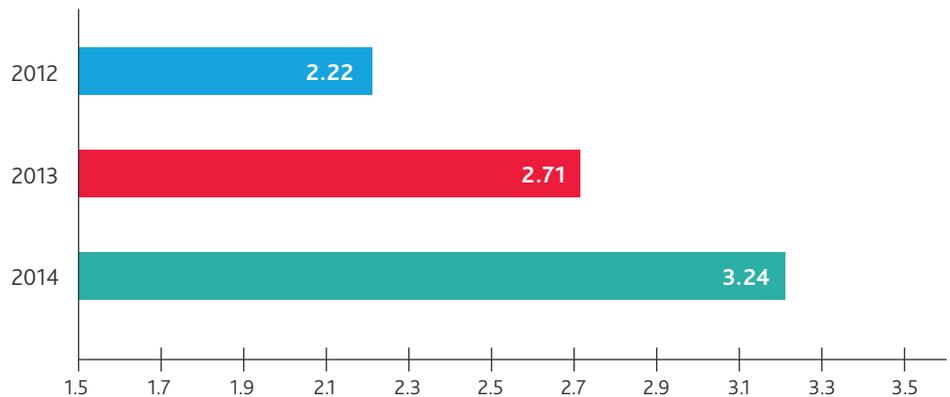
## AVERAGE NUMBER OF EMPLOYEES



## More Cash Reserves, More Time to Invest

As biotech companies look to fund their investment in R&D, they are continuing to grow and prioritize cash reserves. In 2014, biotechs reported an average of \$180.3 million in liquid assets, up 43 percent from 2013 and almost 100 percent from 2012 levels. Biotechs' effective cash management grants them an equivalent of 3.2 years worth of R&D expenditures, marking the highest reserve/R&D spend ratio in the study's history.

## TOTAL YEARS' WORTH OF R&D SPENDING IN LIQUID ASSETS



## Shareholder Returns Boosted IPO Valuations

In 2014, biotech stocks generated an average total shareholder return of 113 percent, up from 97 percent the previous year. Large biotechs delivered the highest returns, averaging 162 percent, up from 79 percent in 2013. Small biotechs delivered a very strong 56 percent in total shareholder return although it was much lower than the 144 percent shareholder return reported in the previous year. Propelled by rising stock prices and greater returns, the average market cap of companies in the study, surpassed the billion dollar mark, reaching \$1.14 billion as of the end of their most recent fiscal year, compared to \$881 million in 2013.

During the first three quarters of 2015, biotechs continued to deliver above average results and increased returns to shareholders, with the NASDAQ Biotechnology Index up 16 percent year-to-date by the end of September, despite some roller-coaster swings. After peaking in July, the biotech sector took a tumble on the heels of heightened controversy over rising drug costs and public proposals for a change in pricing models. Notably, by mid-October, the NASDAQ Biotechnology Index had declined 23 percent from its all-time high in July 2015.

Following the trajectory of the stock market, biotech IPO activity was strong in 2014 and the first part of 2015, boosted by strong returns and investor appetite. In 2014, one-in-four of all U.S. IPOs were biotechs, according to Renaissance Capital. 2015 kicked off with a bang, with \$2.9 billion raised from 29 IPOs in the first half of the year, compared to \$2 billion raised during the first half of 2014. The recent sell-off in the market has temporarily dampened enthusiasm for biotech IPOs and caused valuations to drop.

Many companies who have gone public since September have had to adjust their initial expectations and offer their IPO shares at prices below the initial expected price range. However, according to Barrons, on-balance volume in the sector is rising, indicating that we may see a rally in the future.

## Banner Year for M&A

Buoyed by the strong IPO market and a number of multi-billion dollar deals, 2014 was a record year for biopharma M&A, reaching \$202 billion in total deal value. Increasing scale by adding R&D capabilities and complementary products contributed to the surge in dealmaking.

The M&A frenzy has continued in 2015, with nearly a fourth (23.6 percent) of companies on the NASDAQ Biotechnology Index engaging in M&A in 2015. According to Dealogic data, the first three quarters of the year have seen 302 biopharma deals, totaling \$235 billion.

The sell-off in biotech stocks that occurred in the fall may have created an environment that is favorable for buyers as targets are now more affordable particularly for biotechs with primarily early- or mid-stage assets.



“Despite the current slump in biotech stock prices and IPOs, appetite for M&A remains strong, and we can expect deal activity to continue at a moderate pace. The electoral focus on healthcare reform and public frustration around rising drug prices will create some investor hesitation, but increased excitement about drug development presents an opportunity for future industry growth.”

Aftab Jamil, partner and leader of the Technology & Life Sciences Practice at BDO

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