BIOPHARMA

Conversion, Churn and Burn – Biotech NME’s Cost $1bn, Only 24% Convert to Drugs

• **Bottom Line:** Today we are re-visiting a controversial subject in the biopharmaceutical industry, which is R&D productivity. As a starting point we are updating our prior research (LINK) comparing the R&D productivity of three proto-typical large cap biopharmaceutical companies in our coverage- ABBV (MP), AMGN (MP), and GILD (MP). Compared to two years ago, ABBV (+22%) and AMGN (+13%) have increased the number of new molecular entities (NME’s) in their portfolios, whereas GILD’s portfolio has decreased by 18%. The ultimate scorecard of R&D productivity is 5-year NME conversion (to approved drugs), and the rate declined at both ABBV (36% to 26%) and GILD (40% to 15%), but AMGN showed a significant recovery (7% to 21%). Both ABBV (36% to 46%) and GILD’s (47% to 52%) drop-out rate increased (measured by % of NME’s discontinued) while AMGN’s decreased (75% to 53%). The R&D investment per NME (measured by R&D expenses plus M&A investment divided by number of NME’s) was $5.3bn per NME approval, and $0.9bn per active NME in development. AMGN also had the biggest improvement in their efficiency as their investment per NME declined from $1.35 bn/NME to $0.71 bn/NME, whereas GILD’s investment per NME increased by 22% from $1.25bn to $1.53bn and ABBV’s decreased by 12% from $1.36bn to $1.2bn. The volatility of these assessments of these companies, compared to our analysis two years ago, points to the fluctuations in R&D productivity, at least based on single-timepoint or period assessments.

• **As part of our updated analysis, we have expanded our assessment to include all eight large-cap biopharma companies in our coverage universe ABBV (MP), ALXN (OP), AMGN (MP), BIIB (MP), CELG (MP), GILD (MP), REGN (OP), and VRTX (MP).** The 5 year NME-to-drug conversion rate is about 1 in 4 (24%), and the discontinuation rate remains high (43%); the portfolio turnover rate is an impressive 300% for this group of companies, which could be a contributing factor to the high cost per NME approved of $5.3bn. The average R&D investment per active NME (in pipeline) has come down from $1.3bn 2 years ago to ~$0.9 bn in this analysis. For this group of companies, the average revenue per active NME in 2018 was $0.7bn, and the average enterprise value per active NME in 2018 was $3.7bn. The mature companies in this universe are surprisingly clustered at around $5bn in EV per NME in development, and around ~$1bn in current year revenue per pipeline NME.
In today’s note, we compare these companies by the size of their current R&D portfolios (# of disclosed NME’s), effectiveness of R&D (# of NME approvals and % of NME approvals), R&D efficiency (portfolio turnover, drop-out rate) and R&D cost ($ per NME and per approval). Since almost all management teams have now adopted an origin-agnostic approach to their portfolios, our analysis combines R&D investments and NME’s from inside and outside the company. On most dimensions other than R&D portfolio depth, VRTX (conversion 40%, drop-out 13%, R&D investment per pipeline NME $0.4 bn, R&D/approved NME $2.8 bn) and REGN (conversion 33%, drop-out 36%, R&D/NME pipeline $0.5 bn, R&D/NME approval $2.3 bn) performed more effectively than their rivals, reinforcing the greater effectiveness and efficiency of internally driven R&D strategies. AMGN have improved their R&D effectiveness and efficiency (5-year NME conversion from 7% in 2017 research to 21% in 2019) and R&D/NME in pipeline (from $1.35bn to $0.71bn). ALXN fell behind primarily due to having a high NME drop-out rate (56% vs. eight company average 43%) and high R&D cost per NME in pipeline ($1.5 bn vs. eight company average ~$0.9 bn) after their unsuccessful Synageva acquisition; CELG underperformed peers on nearly all effectiveness, efficiency and cost metrics.
Analysis Limited by Differences in Disclosure, Lack of Consideration of Differences in Value of New Molecular Entities (NMEs) or Credit for non-NME R&D Investments. One of the limitations of this analysis is that it is based on New Molecular Entities (NMEs) as a representation of pipeline assets and value. Pipeline investments that relate to label expansions and generic or biosimilar products are certainly an important part of R&D, but their contributions to value are not reflected in this analysis. Another limitation is differences and changes in pipeline disclosure between companies and in different periods. There is no uncertainty about NME approvals, but active NME numbers vary depending on disclosure. Finally, companies employ different accounting standards for acquisitions and license investments, and while we have captured as many of such costs as possible, such differences could still affect our analysis and conclusions.

ABBV and CELG Have the Deepest R&D Pipelines in Terms of the Number of NMEs in Development in 2018, and CELG Possesses the Highest NME Count in Phase 2 and Later. We used the companies’ own regulatory and investor disclosures, which includes but is not limited to 10-Ks, 10-Qs, earnings releases, conference and other corporate presentations, to assess the number of NMEs in their pipelines and the corresponding development stages. Based on the 2018 materials, we identified 26 separate NMEs in active development by AMGN, which is a nearly 50% increase since 2016 (21 NMEs). Of those NMEs, nearly 50% are in phase 2 or later (Exhibit 1). Likewise, ABBV has 33 NMEs in their pipeline according to their 2018 filings, and the percentage of NMEs in phase 2 and later is ~27%. Most of the other companies in this analysis have NME #’s in development ranging from 10 to 25 with the exception of ALXN which only has 5.

Exhibit 1: Number NMEs in Pipeline by Clinical Stage in 2018

We also examined the ability of these companies to add NMEs to their pipelines in a five-year span and assessed (as best we could) how many of those additional NMEs were discovered internally rather than being acquired through M&A or collaborations. ABBV (NME #=42) and
CELG (NME #=41) had the highest total of additional NMEs from 2014 to 2018. The breadth of the product development portfolios for these companies varies from highly concentrated (e.g., VRTX, #=13) to highly fragmented (e.g., ABBV, # = 42) (Exhibit 2). Though CELG was among the companies with the highest number of additional NMEs over the past five years, most of their NMEs were acquired through M&A or collaborations. CELG’s number of internally discovered NMEs (#=8) was in the bottom tier of the group, which raised some concern about their internal R&D capabilities. On the other hand, REGN was at the opposite end of the spectrum with a 100% in-house discovery rate.

Exhibit 2: Total Number of Additional NMEs in Pipeline by Source 2014 - 2018

Source: Corporate Filings and Presentations; SVB Leerink Research

24% Average Conversion Rate from NME's to Drugs – VRTX, REGN Leading Performers

Conversion rate measures the effectiveness of the company’s efforts to advance their available drug projects to approval over a certain period of time. We choose a five-year development time horizon for this assessment, since it was long enough that a significant portion of named NME’s in the clinic should have reached the market, but is not so long that the whole portfolio would be likely to have turned over for most or all companies. There are many ways to calculate or define conversion rate, but for consistency purposes (as compared to the approach used in prior research), we measured conversion rate based on the number of the named NME’s from 2013 that have reached the market in the ensuing period, and thus ignore the NME’s that were added or acquired during that time.

Over the past five years, these eight large-cap biopharma companies on average were able to convert 24% of their 2013 NMEs to brands, with VRTX being the highest at 40% and REGN the next highest at 33% (Exhibit 3). CELG’s conversion rate was the lowest, at 6%. The average conversion rate was higher among NMEs that were acquired externally, at 32%, compared to 21% for those that we believe were developed internally (Exhibit 4).
Exhibit 3: 2013 R&D Pipeline Conversion Rate (Higher Better)

Source: Corporate Filings and Presentations; SVB Leerink Research

Exhibit 4: 2013 R&D Pipeline Conversion Rate by Source (Internally vs. Externally Discovered)

Source: Corporate Filings and Presentations; SVB Leerink Research
Five-Year Portfolio Turnover ~300%

Among this group of companies the average 5-year portfolio turnover was 300%, with the highest turnover at CELG with 376% and the lowest at AMGN with 174%. The portfolio drop-out rate (or burn rate) across this group of companies averaged 43%. VRTX was the lowest at 13% (Exhibit 5). Churn rate, or pipeline turnover rate, is our assessment of the effectiveness of the company’s vetting procedures on internal and external NME candidates. It is calculated based on the number of NMEs acquired or added during the period plus the number of NMEs discontinued over the period, as a percentage of the number of existing NMEs in 2013. Depending on a company’s specific strategy, development stage, and the macroeconomic environment, turnover in the company’s R&D portfolio is not necessarily a bad thing.

ALXN, BIIB and CELG have higher-than-average churn and burn rates, and ABBV is approximately average for the group. The churn of internally discovered NMEs was lower than for externally discovered NMEs among these eight companies. Portfolio burn was higher for internal NMEs with an average burn rate of 45% compared to 40% for externally sourced NME’s. ALXN had the highest internal burn rate at 67%, while VRTX kept its internal burn rate to 8%.

Exhibit 5: 2013-2018 R&D Portfolio Overall Churn and Burn (Lower Better)

Source: Corporate Filings and Presentations; SVB Leerink Research

5-Year R&D Investment Approaching $200bn across 8 Large Cap Companies

The total product acquisition investment for this group of companies, or “PAI” (five years, eight companies), approached $200 bn, with an average PAI per approved NME of ~$5.3 bn, and an average PAI per NME in development of ~$0.9 bn. While R&D productivity is essential to biopharma companies, capital efficiency (efficiency of capital invested in R&D) is equally important. We attempted to estimate how much an NME costs to acquire (either internally
discovered or externally acquired) and how much it costs to eventually advance to a marketed
drug.

While there are no direct figures that we could use from companies’ financial statements, we
attempted to estimate the total R&D investment by each company for their NMEs. We used GAAP
R&D expense as a good starting point, subtracted accounting adjustments such as R&D
intangible asset amortization, R&D intangible asset impairment, and acquired-in-process R&D (if
included in GAAP R&D) to arrive at “adjusted GAAP R&D,” which we believe is a better
representation of the real internal investment by a company in building its pipeline in a given year.
Finally, by adding M&A investments to adjusted GAAP R&D, we have estimated the total
investment for a given year, which we term product acquisition investment (PAI). Since PAI
swings a lot from year to year based on the lumpiness of M&A events, we used the five-year
cumulative total per company to smooth out such fluctuations (in this analysis 2014 – 2018).
There are certainly limitations to our approach that increase the apparent cost per NME. PAI
includes capital not only invested in NMEs, but also in pursuing new indications, new
combinations, new formulations and other line extensions. Furthermore, we have not stripped out
M&A expenses that go to non-NME assets, such as marketed drugs, infrastructure, platform, etc.

Over the past five years, the eight large-cap biopharma companies collectively spent about $186
bn on product acquisition, and ABBV ($51 bn) and CELG ($44 bn) combined spent nearly $100 bn
with capital being equally deployed between internal R&D investment and external M&A (Exhibit
6). The low external conversion rate of BIIB (11%), REGN (0%) and VRTX (0%) (Exhibit 4) could
be partially explained by their relatively modest external M&A investment (BIIB $1 bn, REGN $0,
VRTX $0) (Exhibit 6). Amgen also invested only modestly for M&A in this period ($2 bn), but
ranked 2nd in external conversion to approved drugs in this period (45% vs. 32% average external
conversion). On the other hand, Amgen’s effectiveness in converting internal programs was
relatively low, with comparatively high internal R&D investment per NME. AMGN’s pipeline
expanded 37% over the past two years (from 19 NMEs in 2016 to 26 NMEs in 2018), and nearly
all of the recent additions appear to have been internally discovered. CELG ranked 2nd in both
R&D and M&A investment among the eight, and were nearly the worst performer in both internal
and external conversion.
Average PAI per Approved NME about $5.3bn, or $4.3bn without CELG. While most of the eight large cap biopharma companies were able to manage their PAI per approved NME to a range of $2 – $5 bn (AMGN, BIIB, REGN and VRTX among the lowest PAI/approved NME near $2.5bn), CELG appeared to be an outlier in this analysis with PAI per approved NME exceeding $20 bn (Exhibit 6). These figures don’t account for differences in value per NME, nor do they consider differences in portfolio stage and timing – for example, Celgene have 5 late-stage NME’s approaching filing or approval in the next 18 months, so the next analysis for their portfolio could look quite different. GILD was the 2nd worst of this group with nearly $10 bn invested for each approved NME, but again, much of GILD’s development investments have been in HIV where they have packaged a finite set of NME’s into different combination products, each requiring independent (and costly) pivotal trials.

Source: Corporate Filings and Presentations; SVB Leerink Research

Source: Corporate Filings and Presentations; SVB Leerink Research

Average of $0.9bn per NME in Development

To acquire one additional NME in development, the eight companies spent from $0.4bn to $1.5bn, with GILD ($1.53bn) and ALXN ($1.47bn) spending 2–3 times more per NME than VRTX ($0.43bn), BIIB ($0.42bn) and REGN ($0.51bn). CELG was about average in PAI per NME in development, largely benefiting from its huge M&A investment (more than $20bn) to acquire ten NMEs (including cell therapies) in 2018.

Exhibit 8: PAI 2014 -2018 / NMEs in Development ($=bn)

Source: Corporate Filings and Presentations; SVB Leerink Research
Pipeline Adequacy, and Pricing, Emerge from Revenue per NME, EV per NME Analysis

Although our primary objective in this research was assessing the updated cost per NME, we also examined the ratio of revenue to NME’s in development and enterprise value (EV) per NME in development. Our hypothesis was that more revenue per NME would suggest fewer opportunities to replace the current sales (fewer “shots on goal”), and that more EV per NME would suggest higher expectations, and higher cost to investors, per NME in development (more costly “shots” on goal).

In general, we would prefer to see more NME’s per $billion of revenue (i.e., lower revenue per NME) and more NME’s per $billion of EV (i.e., lower EV per NME), since this would imply that the company has a relatively well-stocked portfolio (lower revenue per NME) or offers better value for investors (lower EV per NME). This does not imply that the EV is attributable to these NME’s. In fact, in most cases for most of these NME’s, the market is probably giving them very little value, since typically only the most advanced development programs in large cap companies get recognition and value from public market investors.

For this group of companies, the average revenue per active NME in 2018 was $0.7bn, and the average enterprise value per active NME in 2018 was $3.7bn. GILD ($1.6bn) had twice as many NME’s per dollar of revenue compared to the average, and VRTX ($0.2bn), REGN ($0.4bn), CELG ($0.5bn) and BIIB ($0.6bn) were at the low end of the range for peers for revenue per NME (Exhibit 9). At REGN, of the 15 active NMEs in 2018, 4 were in collaboration (shared R&D expenses), and thus likely to support less direct revenue than wholly owned NME’s.

EV per NME is another way to assess the adequacy of the company’s R&D investment. ALXN ($4.7bn), GILD ($5.5bn), ABBV ($5.1bn) and AMGN ($4.9bn) were more expensive in terms of EV/NME, whereas BIIB ($2.8bn), REGN ($2.6bn), VRTX ($2.8bn) and CELG ($1.8bn) were considerably lower than the average on this valuation metric.

Exhibit 9: 2018 Revenue and EV per Active NME in development ($=bn)

Source: Corporate Filings and Presentations; SVB Leerink Research
Lastly, we compared how the group of companies in our current analysis compared to the three companies we examined on similar metrics two years ago (ABBV, GILD and AMGN).

Compared to two years ago, we see an increase in the absolute number of NME’s in the pipeline for ABBV and AMGN, but a decrease for GILD. ABBV’s 22% increase in NMEs in their pipeline (Exhibit 10), the majority of AbbVie’s increase came from phase 1 NMEs, whereas phase 2 and 3 NMEs only increased 10%. AMGN phase 2 and 3 NMEs in pipeline dropped by 44% although their total pipeline grew by 13%, again reflecting a shift towards earlier stage programs.

Exhibit 10: Number of NMEs in Clinical Development Comparison (2017 vs. 2019 Research)

Compared to similar research from two years ago, the average conversion rate for the three companies went down to 21% from 28% (Exhibit 11) - GILD experienced the steepest decline (decreased from 40% to 15%); conversely, AMGN was able to make a successful turnaround (increased from 7% to 21%) and its conversion rate was average for the group in our updated analysis.

Source: Corporate Filings and Presentations; SVB Leerink Research
Pipeline turnover rate increased substantially compared to the prior research across all three companies (average rate increased from 140% to 242%). ABBV’s churn rate more than doubled (increased from 125% to 291%), whereas AMGN’s turnover increased more modestly (from 148% to 174%) (Exhibit 12).

Source: Corporate Filings and Presentations; SVB Leerink Research
The burn rate for these three companies was more consistent from the prior analysis to this one, at around 50%; AMGN managed to reduce their drop-out rate from 75% in the prior research to 53% in this analysis (Exhibit 13).

Exhibit 13: NME 5-Year Burn Rate Comparison (2017 Research vs. 2019 Research)

The average PAI per NME in pipeline for these three companies decreased to $1.15B, or ~13% reduction – AMGN had the deepest decline from $1.35B to $0.71B, or 47% reduction, suggesting a noticeable improvement of capital efficiency in R&D development and M&As (Exhibit 14).

Exhibit 14: PAI/NME in Development Comparison (2017 vs. 2019 Research) ($=bn)

Source: Corporate Filings and Presentations; SVB Leerink Research
Conclusion: Overall, large cap biopharma companies appear to be more effective and cost efficient in managing their R&D and M&As on per NME basis. The 5-year conversion rate to approved drugs is 24% and the burn rate is 43%; on the other hand, the portfolio turnover at 300% still seems profligately high. VRTX and REGN are clearly effectiveness and efficiency leaders across four metrics below (Exhibit 15, Exhibit 16), which may reflect their continued commitment to internal drug discovery and development rather than M&D driven strategies. AMGN made significant improvements in their R&D effectiveness and efficiency compared to two years ago, especially in NME conversion rate, PAI per approved NME and pipeline drop-out rate. Gilead and Celgene are at the bottom of this peer group in terms of their recent NME conversion and churn and burn rates, and are also the lowest in terms of their cost per NME approved and in the pipeline.

Exhibit 15: Rating Board (Rating 0 – 5, 5 Being the Most Favorable)

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*Source: Corporate Filings and Presentations; SVB Leerink Research*
Disclosures Appendix

Analyst Certification

I, Geoffrey C. Porges, MBBS, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

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Explanation of Ratings

**Outperform (Buy):** We expect this stock to outperform its benchmark over the next 12 months.

**Market Perform (Hold/Neutral):** We expect this stock to perform in line with its benchmark over the next 12 months.

**Underperform (Sell):** We expect this stock to underperform its benchmark over the next 12 months.

The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.
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