MARWOOD GROUP®

Life Sciences Investment in the Era of COVID-19
Part 3 of 3: Corporate M&A

EXECUTIVE SUMMARY AND OUTLINE

The COVID-19 pandemic has reshaped each stage of the life science development and investment process. In Part 1 and Part 2 of a three-part series, Marwood addressed the life science venture capital and private equity space, as well as the state of the crossover investor and IPO landscape. In this final installment, Marwood examines the state of the mergers & acquisition (M&A) landscape for end acquirers – manufacturers in the life sciences sector – across the pharmaceutical, diagnostic, and medical device space. The information in Part 3 is broken down into the following sections:

I. Introduction
II. Pharmaceuticals
III. Diagnostics
IV. Medical Devices
V. Conclusion

I. Introduction

As bandwidth returns for M&A transactions in the pharmaceutical, diagnostic, and medical device space, parties are taking a step back to reevaluate the landscape altered by the COVID-19 pandemic and its impact on potential opportunities. A number of considerations that Marwood routinely fields from clients include:

1) *Due diligence*: Pre-COVID due diligence must be refreshed to reflect new impacts to valuation.
2) *Impact of government on life sciences financing dynamics*: As detailed in Parts 1 and 2 of this series, financing dynamics have shifted, from the impact of government non-dilutive financing programs (i.e. BARDA, Operation Warp Speed) to the focus of public and private equity markets.
3) *Legislative focus*: Attention has turned to the immediate effects of COVID-19.
4) *Regulatory review and approval*: The FDA has been actively issuing guidance on the conduct of clinical trials during the public health emergency, in addition to expediting the review of vaccines and treatments for COVID-19.
5) *Federal elections*: Outcomes have the potential to impact pricing and reimbursement.

While the combined M&A value of the life sciences sector plummeted in the first half of this year, the impact of COVID-19 on each subsector has been variable. Parsing the industry across pharmaceutical, diagnostic, and medical device manufacturers, Marwood explores the current M&A landscape, highlighting the financial state of potential corporate acquirers and the major trends shaping the potential for recovery in M&A in the second half of 2020 and beyond.

II. Pharmaceuticals

Pharmaceutical manufacturers have weathered the storm relatively unscathed, placing them in a strong position to pursue M&A. Given redundancies in their sourcing and distribution systems, to date they have faced minimal impact on their manufacturing and supply chain capabilities due to the COVID-19 pandemic. Whereas pharma was expected to demonstrate year-over-year growth in their Q1 earnings due to pandemic-driven prescription filling, recent Q2 earnings have surprisingly beat dire expectations. In addition, manufacturers have expressed optimism in forecasting the balance of the year.

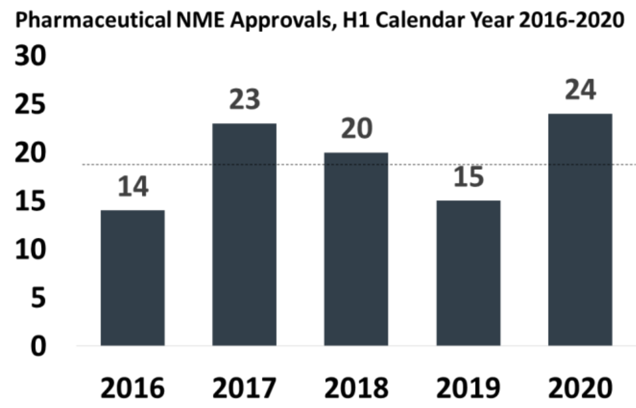

Figure 1: FDA approvals of NMEs, H1 calendar year 2016-2020. Dashed line represents 5 year average of ~19.

A number of examples from the largest pharmaceutical manufacturers provide room for optimism for industry strength driving a return to M&A: While Johnson & Johnson reported declines in their consumer health and medical device business, pharmaceuticals increased by 3.9% and the company increased full year sales and EPS guidance. Pfizer (PFE) and AstraZeneca (AZN) posted stronger-than-expected Q2 earnings, as the former raised and the latter maintained profit guidance. Notably, Pfizer penned a supply deal for 120 million COVID-19 vaccine doses with Japan, while Sanofi (SNY) and GlaxoSmithKline (GSK) scored the largest Operation Warp Speed backing to date, picking up $2.1 billion to advance their vaccine candidate. Sanofi has otherwise raised guidance on earnings per share, despite a 3.4% decline in revenue in Q2, in part due to the vaccine business taking a hit caused by a decline in international travel. While Eli Lilly (LLY) missed its Q2 revenue target, noting a decrease in new patient starts, it beat EPS estimates and raised full-year revenue forecasts. Notably, Lilly recently announced that it is initiating a Phase 3 Trial of LY-CoV555 for prevention of COVID-19. And although Novartis (NVS), Roche (RHHBY), and Merck (MRK) posted disappointing quarters, their year-end guidance has remained relatively steady. This is a far cry from the fog of Q1, when the uncertainty of the pandemic had led several to hold back end of year guidance entirely.

The COVID-19 pandemic has neither put a damper on unrelated FDA approvals. New drugs (new molecular entities (NMEs)) have held steady in the first half of 2020, despite the potential for disruption. In the four quarters between Q3 2019 and Q2 2020, 59 new molecular entities have been approved by the FDA, topping the 55 in the parallel 2018-2019 period. Indeed, the pace of approvals in Q1 and Q2, was on par, if not above the five-year average for these quarters **(Figure 1)**.

Yet, despite the health of the largest players and consistent approval rate, the sector has only seen three $1B+ deals in 2020 **(Figure 2)**.[1] A number of factors may be at play, most apparent of which is an abrupt inward focus of manufacturers on the initial stages of the pandemic. As bandwidth for M&A has returned, manufacturers are reconsidering the applicability of their pre-pandemic strategic priorities to the now-shifted landscape. Beyond a drop in deal volume, valuation may also be at play. Life sciences companies have been raising capital as valuations have been strong. A double-edged sword, strong valuations may also be impeding M&A. While this may be particularly the case for

[1] Global corporate M&A deals. Pitchbook *Accessed July 15, 2020*.

Target	Acquirer	Announced	Completed	Value
Forty Seven	Gilead Sciences	March 2	April 7	$5.0B
Corvidia Therapeutics	Novo Nordisk	June 11	In Process	$2.1B
Portola Pharma	Alexion Pharma	May 5	July 2	$1.8B
Glycom	Koninklijke	February 21	April 1	$0.8B
Stemline Therapeutics	Menarini/Berlin-Chemie	March 4	June 10	$0.7B

Figure 2: Largest pharmaceutical corporate M&A deals of Q1 and Q2 of 2020.[1]

cash-flush large caps, small and medium cap pharmaceutical companies and particularly nonrevenue-driven biotechs may be a more immediate target.

Looking forward, a number of factors – beyond the health of pharmaceutical manufacturers in a recessionary market – point toward rebounding M&A activity:

a. Inexpensive Corporate Debt Contributing to Cash for Acquisitions

At the onset of the COVID-19 pandemic, as central banks implemented unprecedented monetary policy actions and interest rates reached historic lows, life sciences companies' appetite for corporate debt mirrored a larger industry-wide surge. In context, life sciences companies in the US have issued more debt in the first half of 2020 than in all of 2019. Among pharmaceutical companies, the greatest issuance has come from Pfizer Inc. and Merck & Co. Inc., issuing $5.25 billion and $4.5 billion, respectively. Amgen (AMGN) issued and sold $4 billion of senior notes in May and $4.96 billion of senior notes in February. While most of these companies plan to use proceeds from their debt issuances to repay existing debt (and for general corporate purposes), it is worth noting that large cash balances are usually not appreciated by investors who would rather see it put to work. As such, it is plausible to assume that many seem poised to make acquisitions, leading to speculation about a possible M&A revival in the industry when the pandemic subsides. Most evident of this trend, Pfizer completed the issuance of its first-ever sustainability bond worth $1.25 billion in March. The sustainability bond will be used to support efforts to address the coronavirus pandemic and the threat of antimicrobial resistance.

b. Divestiture Contributing to Cash

Marwood expects there to be further divestitures within the life sciences space as companies are forced to prioritize and manage a limited set of R&D resources. Many companies could look to divest assets outside of their core competencies, in order to obtain the capital necessary to complete development of their high priority projects. For example, Takeda recently divested its portfolio of non-core products in Latin America to Hypera (HYPMY) for $800M and their portfolio of OTC and non-core assets and manufacturing sites to Orifarm for $700M.

c. Pipeline Replenishment

Having spent the last several months playing defense with internal operations, larger pharma players are emerging, relatively unscathed, to an alternated strategic landscape. The change and uncertainty in terms of supply chains, regulatory approvals, and fast-tracked priorities may contribute to new M&A strategies. In particular, given the less stable market, companies may be willing to take more drastic action, from the perspective of both buyer and seller. In the current environment, in which achievement of clinical milestones could be delayed by COVID-19, a drop in target values may encourage some opportunistic acquisitions that were out of reach just months prior to the pandemic.

d. COVID-19 Impacting Pharma M&A Considerations

The demand for COVID-19 vaccines and therapies is driving M&A, both in terms of R&D assets and manufacturing capability. Novavax (NVAX) is buying Czech Republic-based Praha Vaccines for $167M. The two companies will work with vaccine producer, Serum Institute of India, to develop a coronavirus vaccine. The acquisition includes a biologics manufacturing facility and assets in Bohumil, Czech Republic. Notably, through the federal Health and Human Services (HHS) program, Operation Warp Speed, Novavax will receive up to $1.6B in nondilutive financing for the development of COVID-19 vaccine. Merck completed its deal for vaccine maker, Themis, in June. The agreement commits Merck to an investment of up to $200 million (€180 million) in milestones to secure vaccines against an undisclosed target. A notable exception to COVID-19-driven M&A, may be AstraZeneca's failed attempt to approach Gilead (GILD) about what could have been the largest healthcare deal on record. AstraZeneca is helping to manufacture a COVID-19 vaccine developed at the University of Oxford. Gilead has garnered investor interest for its antiviral drug for Covid-19, Remdesivir. Beyond shareholder objection, distraction from AstraZeneca's COVID-19 vaccine efforts may have contributed to the demise of this deal.

III. Diagnostics

Diagnostics have had a strong year. Large diagnostic companies have performed well in the first half of 2020, despite earlier concerns regarding a drop-off in non-COVID-19 tests. This places them in a strong position to consider M&A opportunities. Thermo Fisher (TMO), whose diversified portfolio is negatively exposed to disruptions to healthcare providers and other business, still reported growth of 10% in Q2 given revenue from PCR-based tests and other products and services involved in response to COVID-19. Less diversified diagnostic companies demonstrated stronger growth. In addition to Thermo Fisher, Luminex (LMNX), GenMark (GNMK), and Quidel (QDEL) each reported double-digit growth in the second quarter. The results suggest sustained demand for COVID-19 tests is offsetting disruption to other parts of the diagnostic sector.

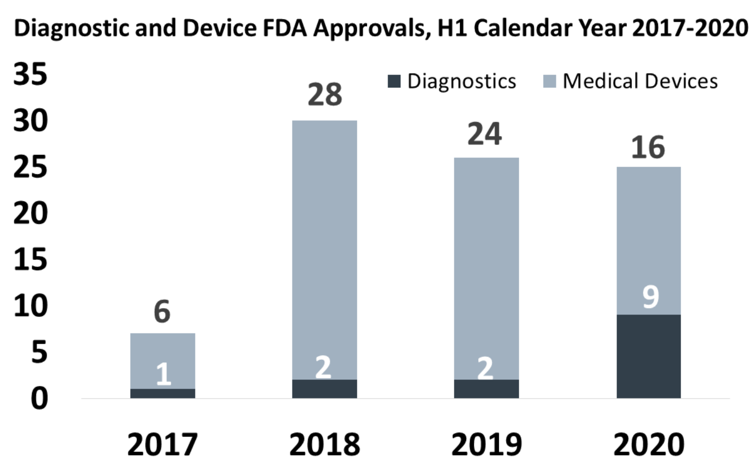

Figure 3: Largest diagnostic and medical device FDA approvals, H1 calendar year 2017-2020

Target	Acquirer	Announced	Completed	Value
Qiagen	Thermo Fisher	March 3	In Process	$11.8B
Archer DX	Invitae	June 22	June 22	$1.4B
Blueprint Genetics	Quest	January 22	January 22	$123.6M
Ellex	Lumibird	*Dec 23, 2019*	June 30	$68.8M
Exalenz	Meridian Bloscience	February 19	April 30	$47.3M

Figure 4: Largest diagnostic corporate M&A deals of Q1 and Q2 of 2020.[1]

Although unrelated to COVID-19 applications, diagnostic approvals of lab tests in Q1-Q2 far outpaced approvals during the period in the past four years, even as device approvals lagged all but 2017 **(Figure 3)**.

In addition, the sector boasts the largest life sciences acquisition of the year, thus far, with Thermo Fisher's $11.5B acquisition of Qiagen **(Figure 4)**. Notably, both Thermo Fisher and Qiagen are developing COVID-19 diagnostics. However, large acquisitions are still occurring in other spaces outside of infectious disease. Invitae announced it was buying Archer DX for $1.4B to bolster work in the cancer diagnostics space.

A number of additional factors tied to enthusiasm in the COVID-19 market point toward continued growth in diagnostic manufacturer M&A activity:

a. Inexpensive Corporate Debt Contributing to Cash for Acquisitions

Similar to the pharmaceutical sector, diagnostics companies are taking advantage of historically low interest rates to fuel cash balances that can be used for acquisition. In March, Thermo Fisher issued $2.2B in debt to partly fund the Qiagen acquisition.

b. COVID-19 as Catalyst for Consolidation

The leadership at Quest has indicated that the pandemic served as a potential catalyst for consolidation of regional laboratories. Notably, the company is seeking acquisition targets among hospital labs and smaller diagnostic facilities, having recently acquired a substantial portion of the diagnostic labs from Houston's Memorial Hermann Health System. Smaller regional laboratories have had their own efficiency challenges, from supply chain to managing volume, which provides for opportunistic acquisition.

IV. Medical Devices

In contrast to pharmaceuticals and diagnostics, medical devices, particularly implantables, have faced strong headwinds. Prior to the global pandemic, the medical device implant industry had been growing at high single-digit rates, driven by elective surgeries for knees, hips, bariatric, neuromodulation, and cardiovascular devices. In the presence of a global recession, medical device implants have been among the biggest losers, as elective surgeries have been delayed and struggle to return to pre-recession levels as the pandemic smolders on, nationally.

Examples of the decline can be seen in the Q2 results. Smith+Nephew (SNN) reported knee implant sales were down 47.8%, hip implant revenue dropped 28.1%, and sports medicine joint repair revenue dropped 33.6%. Similarly, while Johnson & Johnson posted Q2 results that beat consensus, their

Target	Acquirer	Announced	Completed	Value
Dermira	Eli Lilly	January 10	February 20	$1.1B
ArthroSurface	Anika Therapeutics	January 6	Feburary 3	$100M
Novabone Products	Halma	January 27	January 27	$137M
Artegraft	LeMaitre Vascular	June 23	June 23	$90M
Attune Hearing	Amplifon	January 9	February 6	$38m

Figure 5: Largest medical device corporate M&A deals of Q1 and Q2 of 2020.[1]

medical device business spanning surgery (Ethicon), cardiovascular and specialty (Biosense Webster) and orthopedic (DePuy Synthes) saw year-over-year sales declines of 33.9%. Other specialties have also seen significant declines. Abbott's (ABT) device sales, which span cardiovascular, diabetes, neuromodulation, and diagnostic systems declined 21.2% compared to the previous year. Similarly, equipment makers for minimally invasive surgeries took a hit, such as Medtronic's (MDT) Minimally Invasive Therapies Group (Covidien).

Furthermore, FDA clearances of medical devices in Q1-Q2 lagged approvals during the period in the previous four years, even as combined device and diagnostic clearances were on par with Q1-Q2 2019 **(Figure 3)**.

In line with the consequent uncertainty of delayed elective surgeries, the volume and value of medical device deals fell sharply in Q1 and Q2, with only a single $1B+ deal while most others were in the $100M range **(Figure 5)**. Indeed, the average size of completed mergers is lower than at any point in the past decade. This becomes particularly evident when teasing out the diagnostics space, where deals included the $11.8B acquisition of Qiagen (QGEN) by Thermo Fisher and the $1.4B acquisition of Archer DX by Invitae (NVTA).

However, there is optimism that Q2 marked the bottom of the procedural abyss. For example, Boston Scientific (BSX), a manufacturer of devices for interventional medical specialties, noted that despite a 29% decline in sales, the company saw sequential business improvement across April, May, and June as surgeries could not be delayed indefinitely. Similarly, orthopedics and dental also demonstrated faster than expected recovery in procedures during Q2. An understanding of the pace and means through which deferred procedures will unwind and consequent impacts on volume and revenue will be crucial in evaluating appetite and targets for M&A in the medical device space.

V. Conclusion

As the COVID-19 pandemic continues to smolder, the implications to the life sciences industry is only beginning to play out in the private and public equity space, as well as corporate M&A. As a leading healthcare-focused advisory firm, Marwood advises life sciences investors and corporations in conducting market diligence, strategizing market access, and managing product life cycles leveraging direct insight into federal and state policy, finance, corporate strategy and intra-institutional dynamics.

About the Author

This article was prepared by Marwood's Life Sciences practice group. Drawing on the collective expertise of its seasoned healthcare professionals, Marwood leverages the team's 100+ years of combined experience in the life sciences sector to inform a multi-dimensional analysis of healthcare's most pressing challenges for investors and corporate strategists.

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