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An empirical study of the impact of mergers and acquisitions on pharmaceutical innovation: Insights from drug launches

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ABSTRACT

Despite the extensive theoretical literature on the impact of mergers and acquisitions (M&As) on pharmaceutical innovation, empirical research to measure such impact is limited and has largely focused on innovation outcomes that do not directly impact patients. In this article, we empirically investigate the association between M&As and two measures of innovation that directly impact patients: the likelihood of drug launch overall and the likelihood of novel drug launch. Using data on drug development events and M&As in the pharmaceutical industry, we first document a large, positive, and statistically significant association between M&As and our measures of innovation. To better understand these findings, we hypothesize one possible economic "mechanism" that may explain the observed relationship. That is, we hypothesize that acquisitions of small target firms by large acquiring firms provide the acquired small firms with resources (e.g., additional funding, prior experience, and expertise) to bring their drug projects to market, therefore increasing the likelihood of (novel) drug launches. We then examine whether the data contain empirical support for this hypothesized mechanism. We compare the likelihood of launch of (novel) drug projects belonging to small firms when they are acquired by large firms versus when they are acquired by other small firms. We find a higher likelihood of (novel) drug launch in the former group relative to the latter, which provides support for the hypothesized mechanism.

I. Introduction and motivation

1. The theoretical economic literature identifies many mechanisms through which mergers and acquisitions (M&As) can impact innovation in the pharmaceutical industry.[1] For example, M&As can increase innovation by alleviating the financial constraints of the target companies,[2] creating economies of scale and scope in research activity,[3] and improving project selection.[4] However, M&As may also decrease innovation by reducing firms' incentives to develop and launch competing drugs.[5]

2. Despite the extensive theoretical literature on the mechanisms through which M&As can impact pharmaceutical innovation, empirical research to measure such impact is limited. Furthermore, the few empirical studies have found mixed results, depending on the measure of innovation considered, the period analyzed, and the set of transactions studied.[6] Measures of innovation considered include patent counts, research and development (R&D) expenditures, and progression through clinical trial phases.[7] However, these are not measures of innovation that most directly impact patients.

3. By contrast, patients most directly benefit from pharmaceutical innovation when new drugs are launched, particularly when these drugs have the potential to offer substantial therapeutic improvements over existing ther-

* The views expressed herein are those of the authors and do not necessarily reflect the views of Cornerstone Research.

1 For a review of the economic literature on the mechanisms and effects of M&As on innovation in the pharmaceutical industry, *see* L. Cattivelli, A. Cojoc, P. Kovacheva and M. Salgado, The Impact of Pharmaceutical M&A on Innovation: Insights from the Literature and Gaps Remaining, *Concurrences* No. 3-2024, art. No. 119352.

2 Fumagalli et al. (2022) argue that an acquisition of a start-up by an incumbent firm can lead to "*the development of a project that would otherwise never reach the market* (. . .) *because the incumbent has availability of resources – managerial skills, market opportunities, capital – that the target firm lacks*." Erel et al. (2015) analyze a sample of European acquisitions and find that acquisitions can relieve financial constraints in target firms, especially for smaller targets. *See* C. Fumagalli, M. Motta and E. Tarantino, Shelving or Developing? The Acquisition of Potential Competitors under Financial Constraints, *Centre for Studies in Economics and Finance Working Paper* No. 637, February 2022, at 1–2; I. Erel, Y. Jang and M. S. Weisbach, Do Acquisitions Relieve Target Firms' Financial Constraints?, *The Journal of Finance*, Vol. 70, No. 1, 2015, pp. 289–328.

3 For example, Henderson and Cockburn (1996) find that larger research efforts are more productive. The authors find that this is due to economies of scale (e.g., because of substantial fixed-cost investments) and economies of scope (e.g., knowledge spillovers). *See* R. Henderson and I. Cockburn, Scale, Scope, and Spillovers: The Determinants of Research Productivity in Drug Discovery, *RAND Journal of Economics*, Vol. 27, No. 1, 1996, pp. 32–59.

4 For example, Jullien and Lefouili (2018) find that mergers can increase innovation due to internalization of knowledge spillovers. *See* B. Jullien and Y. Lefouili, Horizontal Mergers and Innovation, *Journal of Competition Law & Economics*, Vol. 14, No. 3, 2018, pp. 364–392.

5 C. Cunningham, F. Ederer and S. Ma, Killer Acquisitions, *Journal of Political Economy*, Vol. 129, No. 3, 2021, pp. 649–702; M. Motta and E. Tarantino, The Effect of Horizontal Mergers, When Firms Compete in Prices and Investments, *International Journal of Industrial Organization*, Vol. 78, 2021, pp. 1–20; J. Haucap, A. Rasch and J. Stiebale, How Mergers Affect Innovation: Theory and Evidence, *International Journal of Industrial Organization*, Vol. 63, 2019, pp. 283–325.

6 For a review of these findings, *see* Cattivelli et al., *supra* note 1.

7 Haucap et al. (2019) use the number of patents filed by the target and acquirer as a measure of innovation. Grabowski and Kyle (2008) leverage project development stage advancement in a forward-looking five-year window as a measure of innovation. Schutz (2023) study changes in the number of filed patents, R&D spending, and the number of drugs in clinical trials. Meder (2019) explores the impact of M&As on newly initiated drug projects. Bonaimé and Wang (2024) measure innovation by new drug approvals by the FDA. *See* Haucap et al., *supra* note 5; H. Grabowski and M. Kyle, Mergers and Alliances in Pharmaceuticals: Effects on Innovation and R&D Productivity, in *The Economics of Corporate Governance and Mergers*, K. Gugler and B. Yurtoglu (eds.), Edward Elgar Publishing, Cheltenham, 2008, pp. 262–288; S. Schutz, Mergers, Prices, and Innovation: Lessons from the Pharmaceutical Industry, Working Paper, 2023; H. Meder, Product Developments Post-M&As - Research Trajectory of Pharmaceutical Firms, Working Paper, 2023; A. Bonaimé and Y. Wang, Mergers, Product Prices, and Innovation: Evidence from the Pharmaceutical Industry, *The Journal of Finance*, Vol. 79, No. 3, 2024, pp. 2195–2236. The closest papers to ours that we are aware of are Cunningham et al. (2021), which study the impact of M&As on the likelihood that a drug project is terminated before launch, and Wabiszewski (2024), which studies acquisitions of biotechnology start-ups by large pharmaceutical companies and how this impacts start-ups' likelihood of receiving regulatory approval for their drug technology. *See* Cunningham et al., *supra* note 5; H. Wabiszewski, Startup Acquisitions and Innovation in the Biopharmaceutical Industry, Working Paper, 2024.

apies or address unmet medical needs.[8] Novel, high-value-added treatments can improve patient outcomes, enhance quality of life, and fill critical gaps in medical care where no effective therapies previously existed.[9]

4. We contribute to the literature by empirically analyzing the relationship between M&As and innovation in the U.S. using measures of innovation that directly impact patients. We measure innovation in two ways: (i) as the likelihood of drug launch, and (ii) as the likelihood of launch of novel drugs (i.e., drugs that have the potential to serve important unmet patient needs or provide a substantial improvement over existing treatments, as explained in greater detail in Section III).

5. Relying on two large datasets—one that tracks drug development events in the U.S. and another that tracks M&As in the U.S. pharmaceutical sector—we first document a large, positive, and statistically significant association between M&As and the likelihood of both drug launch overall and novel drug launch. That is, we show that acquired drug projects through M&As are more likely to launch, and to launch as novel drugs, than non-acquired ones. We then investigate one possible causal mechanism that may explain this observed relationship ("hypothesized mechanism"). Specifically, we hypothesize that acquisitions of small firms by large firms provide small firms with resources to bring pipeline drug projects to market, therefore increasing the likelihood of (novel) drug launches. These resources may otherwise be difficult for small firms to obtain. Our datasets allow us to test whether there is empirical evidence consistent with this hypothesis. We find that drug projects of small target firms, and especially novel drug projects of small target firms, are more likely to be launched if the target is acquired by a large firm rather than by a small firm. This finding is consistent with and provides empirical support for our hypothesized mechanism.

6. The remainder of this paper is organized as follows: Section II explains our research agenda and our proposed hypothesis about the relationship between acquiring firm size and innovation. Section III describes the data as well as our measures of drug novelty and firm size. Sections IV and V present our two main results. Section VI discusses several robustness checks. Section VII describes topics for further research.

II. Research agenda

7. To study the impact of M&As on drug launches, we first compare (i) drug projects in which the firm that originated these projects ("originator firm") was acquired prior to the launch or discontinuation of these projects to (ii) drug projects in which the originator firm was not acquired. Between these two groups, we compare the respective share of drug projects that are eventually launched—i.e., made available for the treatment of patients.[10] Then, we perform the same comparison, focusing on drug projects that received expedited review designation ("ERD") from the Food and Drug Administration (FDA), which, as we explain below, is one way to measure the novelty of a drug. We find that drug projects that undergo M&As have a higher likelihood of launching relative to drug projects that do not. Furthermore, we find that drug projects that undergo M&As have a higher likelihood of launching as novel drugs (i.e., after receiving an ERD) relative to those drug projects that do not undergo any M&A.

8. Then, we consider one possible causal mechanism that could explain these findings. A common type of M&A in the pharmaceutical industry is one in which a large, established firm acquires a smaller firm with no prior experience in launching drugs (e.g., a biotech start-up).[11] As previewed above, we hypothesize that M&As of this type may explain the observed increase in the likelihood of drug launches for acquired drug projects relative to non-acquired drug projects. Academic literature has found that while small firms may be successful at initiating drug projects, they may not be well equipped in late-stage R&D and commercialization.[12] Through ac-

8 For example, Kisqali (ribociclib) treats certain types of breast cancer and was granted a breakthrough therapy designation by the Food and Drug Administration (FDA) due to positive results in Phase III clinical trials demonstrating the advantages of Kisqali combination therapy as compared to hormone (endocrine) therapy alone. Similarly, Revex (nalmefene) treats acute opioid overdoses and was granted fast-track approval by the FDA, as it had the potential to fill a large unmet medical need. Similarly, the well-known COVID-19 vaccine from Moderna received a fast-track approval to address the urgent need for a vaccine. *See* Novartis press release, Novartis Kisqali® Received FDA Breakthrough Therapy Designation for Initial Endocrine-Based Treatment in Premenopausal Women with HR+/HER2- Advanced Breast Cancer, 3 January 2018, https://www.novartis.com/news/media-releases/novartis-kisqali-received-fda-breakthrough-therapy-designation-initial-endocrine-based-treatment-premenopausal-women-hrher2-advanced-breast-cancer; FDA press release, FDA Approves First Nalmefene Hydrochloride Auto-Injector to Reverse Opioid Overdose, 7 August 2024, https://www.fda.gov/news-events/press-announcements/fda-approves-first-nalmefene-hydrochloride-auto-injector-reverse-opioid-overdose; Moderna press release, Moderna Receives FDA Fast Track Designation for mRNA Vaccine (mRNA-1273) Against Novel Coronavirus, 12 May 2020, https://www.reuters.com/article/business/healthcare-pharmaceuticals/moderna-receives-fda-fast-track-designation-for-mrna-vaccine-mrna-1273-against-n-idUSASA00POE/.

9 *See* A. A. Levine, D. E. Enright, K. A. Clifford, S. Kowal and J. D. Chambers, Are Drug Novelty Characteristics Associated with Greater Health Benefits?, *Applied Health Economics and Health Policy*, Vol. 22, No. 6, 2024, pp. 827–832, at 831 ("*Drugs with novelty characteristics given special consideration by* [health technology assessment] *agencies conferred larger health gains than drugs without these characteristics. Our findings suggest that the drugs prioritized via FDA-expedited programs do result in health benefits to patients (as measured by the* [quality-adjusted life-years]*) as intended*").

10 Hereon, we use the term "drug projects" to refer to drug projects in a firm's drug development pipeline.

11 *See* Wabiszewski *supra* note 7, at 1 ("*While a few early biotechnology startups such as Genentech, Amgen, and Biogen grew in scale to rival that of big pharma, many startups remained small and focused on drug discovery and early-stage development. As a result, many of the drugs and technologies originally developed by startups are then licensed or acquired by larger firms to carry out late-stage development. By the late 2010s, startups were originating around 70% of the drugs being developed in the U.S. Big pharma, defined here as the top 40 firms by revenue in a given year, has been increasingly using acquisitions as a way to fill their development pipelines. Consequently, acquisition has become an important exit strategy for startups, with around 55% of venture capital-funded biotech startups exiting via shutdown, 24% via acquisition, and 21% via IPO from 2005 through 2015*"). In the context of diabetes, Malek et al. (2024) find that almost one third of antidiabetic drug projects were acquired from small firms by large or biotech firms. *See* J. Malek, M. Newham, J. Seldeslachts and R. Veugelers, Acquiring R&D Projects: Who, When, and What? Evidence from Antidiabetic Drug Development, *DIW Berlin Discussion Papers* No. 2073, 2024.

12 Wabiszewski (2024) notes how it is common for biotech start-ups to focus on early-stage development, producing promising drug projects that are then acquired by larger firms. *See* Wabiszewski, *supra* note 7, at 10–11 ("*While several biotechnology firms including Genentech, Amgen, and Biogen came to be fully vertically integrated and joined big pharma, many remained relatively small, closely aligned with the academic institutions from which their*

quisitions, large firms may provide smaller firms with assistance in later stages of development (including funding for costly late-stage clinical trials);[13] expertise in navigating the complex and cumbersome regulatory approval process;[14] and manufacturing infrastructure.[15] In what follows, we will use the term "resources" to refer to any such support that large acquiring firms can provide small target firms. These resources may be particularly beneficial in the development of novel drug projects, which can be riskier, costlier, and more time-intensive than the development of other drugs.[16] Hereon, we will refer to this as the "hypothesized mechanism."

9. We empirically investigate this hypothesized mechanism. That is, we analyze whether the data support the hypothesis that large firms acquiring small firms explains the increased likelihood of (novel) drug launches for acquired versus non-acquired drug projects. To this end, we compare the likelihood of (novel) drug launches for drug projects developed by small firms and acquired by large firms with the likelihood of drug launches for drug projects developed by small firms and acquired by other small firms. The hypothesized mechanism predicts that acquisitions of small firms by large firms would be more likely to enhance small firms' access to resources for launching (novel) drug projects than acquisitions of small firms by other small firms. That is, if this mechanism contributes to the impact of M&As on drug launches, M&As in the first group (i.e., large firms acquiring small firms) would have a higher likelihood of drug launches relative to the second group (i.e., small firms acquiring small firms). Due to the added complexities associated with the launch of novel drugs, under the hypothesized mechanism, we would expect to see a greater association between acquiring firm size and drug launch when looking at novel drug projects than when looking at drug projects overall.

III. Data

10. We built a drug project-year panel dataset that combines drug development events from Citeline's Pharmaprojects dataset ("Drug Development Data")[17] and M&A events from Clarivate's Cortellis Deals Intelligence dataset ("Deals Data").[18] We use these data to track the U.S. development and changes in ownership over time and across companies for 33,099 drug projects initiated globally between 1995 and 2024.

researchers came, and focused on drug discovery and early-stage development. (. . .) As a result, a vertical structure came to dominate the industry. Biotechnology firms engaged in drug discovery and proved the viability of a drug candidate in preclinical research and early-stage clinical development. Promising drug candidates may then be licensed out to or acquired by a downstream big pharma firm that can continue its development in the larger, more capital-intensive phases of R&D"). In the market for oncology treatments, Kennedy et al. (2023) find that small firms are more likely to originate first-in-class oncology drugs but rely on large firms for late-stage development and approval. *See* K. H. Kennedy, K. Gomez, N. J. Thovmasian and D. C. Chang, Small Biotechs versus Large Pharma: Who Drives First-in-Class Innovation in Oncology?, *Drug Discovery Today*, Vol. 28, No. 2, 2023, pp. 1–7, at 1 ("[L]*arge pharma was the sole originator of only 14% of FIC* [first-in-class] *cancer drugs, whereas small biotechs originated 46%, and academic labs 14%. However, origins tell an incomplete story: large pharma companies launched or were involved in launching 76% of FIC cancer drugs. (. . .) Thus, although biotechs and academia do originate more drugs, large pharma remains important in shepherding drugs through clinical development and approval*").

13 The average cost of Phase I clinical trials is USD 25.3 million, while the average cost of Phase III clinical trials is USD 255.4 million (in 2013 dollars). *See* J. A. DiMasi, H. G. Grabowski and R. W. Hansen, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, *Journal of Health Economics*, Vol. 47, 2016, pp. 20–33, at 24.

14 *See* R. A. Moscicki and P. K. Tandon, Drug-Development Challenges for Small Biopharmaceutical Companies, *New England Journal of Medicine*, Vol. 376, No. 5, 2017, pp. 469–474, at 469 ("*In a context in which only approximately 10% of clinical programs result in drugs that achieve regulatory approval, small-company clinical programs may have an even lower rate of success than that of large companies owing to limited internal experience in clinical development and limited infrastructure, which may also affect manufacturing and clinical supply. However, these challenges are largely overshadowed by limited resources and funding, which in turn fuel demand for short timelines owing to the need to demonstrate progress to investors*"); Wabiszewski, *supra* note 7, at 22–23 ("*Further, a higher FDA approval probability suggests that big firms may benefit from having more experience or greater financial resources dedicated to interacting with the FDA and navigating the regulatory process. Therefore, for a project with the same characteristics, a project developed by big pharma is more likely to be approved than a project developed by a non-acquired startup*").

15 *See* E. Petrova, Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development, in *Innovation and Marketing in the Pharmaceutical Industry*, M. Ding, J. Eliashberg and S. Stremersch (eds.), Springer, New York, 2014, pp. 19–81, at 47 ("*Efficiencies in operations are hard to attain for* [small biotech] *firms. Even if they manage to successfully take their innovative products through clinical trials, small biotech firms may not have the requisite commercialization capabilities to go to market. Therefore, the stages of the innovation process that need large-scale efforts combined with access to considerable capital, infrastructure, and proprietary assets (e.g., clinical trials, manufacturing, or marketing) might be the stages best delegated to other industry participants*").

16 Krieger et al. (2022) find that novel drug candidates are less likely to launch relative to non-novel drug candidates. Similarly, Thomas et al. (2021) find that novel drugs have lower FDA approval rates as compared to "off-patent" products (i.e., a drug that is similar to a brand medicine that no longer has a patent). *See* J. Krieger, D. Li and D. Papanikolaou, Missing Novelty in Drug Development, *The Review of Financial Studies*, Vol. 35, No. 2, 2022, pp. 636–679; D. Thomas, D. Chancellor, A. Micklus, S. LaFever, M. Hay, S. Chaudhuri, R. Bowden and A. W. Lo, Clinical Development Success Rates and Contributing Factors 2011–2020, *Biotechnology Innovation Organization*, February 2021, at 15. Using our drug development dataset described in greater detail in Section III, we find that the development of novel drugs is more time-intensive. That is, among drugs that launched, we find that drugs that receive an expedited review designation ("ERD") from the FDA (which is our measure of drug novelty described in Section III) have an average time between initiation and launch that is three years longer than drugs that do not receive an ERD (9.8 years versus 6.8 years). Academic research has also found that innovative drugs designated as breakthrough therapies by the FDA (one type of ERD) tend to be more costly to develop relative to those that did not receive this designation. *See* N. Olchanski, P-J. Lin, W.-S. Yeh, S. Kowal and J. T. Cohen, When Are Breakthrough Therapies Cost-Effective?, *Journal of Managed Care & Specialty Pharmacy*, Vol. 28, No. 7, 2022, pp. 732–739.

17 Citeline's Pharmaprojects is a data source widely used in prior research studying pharmaceutical innovation and drug development. *See*, e.g., Cunningham et al., *supra* note 5; C. P. Adams and V. V. Brantner, Spending on New Drug Development, *Health Economics*, Vol. 19, Issue 2, 2010, pp. 130–141; M. E. Blume-Kohout and N. Sood, Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development, *Journal of Public Economics*, Vol. 97, 2013, pp. 327–336; L. Branstetter, C. Chatterjee and M. J. Higgins, Starving (or Fattening) The Golden Goose?: Generic Entry and the Incentives for Early-Stage Pharmaceutical Innovation, *NBER Working Paper* No. 20532, 2014; D. Filson and A. Oweis, The Impacts of the Rise of Paragraph IV Challenges on Startup Alliance Formation and Firm Value in the Pharmaceutical Industry, *Journal of Health Economics*, Vol. 29, Issue 4, 2010, pp. 575–584; M. G. Kyle, Pharmaceutical Price Controls and Entry Strategies, *The Review of Economics and Statistics*, Vol. 89, No. 1, 2007, pp. 88–99. The dataset compiles publicly available information (from public releases, regulatory filings, patent applications, conference materials, etc.) for nearly 100,000 drug projects initiated worldwide since 1969 and records their development progress through clinical testing, regulatory review and approval, to launch or discontinuation. Pharmaprojects provides information about each drug project, including the current owner, the originator, and the diseases targeted by the drug project, and the timing of critical points in development, including initiation, clinical trial progression, approval, and launch. It also tracks information on and timing of events that happen during a drug project's development (e.g., initiation, obtaining an expedited review designation, approval, launch in a given country, etc.), which we will refer to as "development events." We focus our analysis on drug projects that were initiated between 1995 and 2024 and that experienced at least one development event after their initiation. *See* Table 1.

18 The Cortellis Deals Intelligence dataset (formerly Thomson Reuters Recap) has been used in multiple studies on financial deals involving pharmaceutical companies. *See*, e.g., Cunningham et al., *supra* note 5; J. Eklund and R. Kapoor, Mind the Gaps: How Organization Design Shapes the Sourcing of Inventions, *Organization Science*, Vol. 33, No. 4, 2022, pp. 1319–1339. The dataset collects information about the timing of and parties involved in pharmaceutical M&As in the U.S.

11. The Drug Development Data reports the timing of key development events for each drug project. These include drug initiation, regulatory approval, and date of U.S. launch. Hence, this dataset allows us to identify whether a drug was launched in the U.S. and when.

12. Additionally, the Drug Development Data has information on which drugs obtained ERD by the FDA.[19] ERD can be a proxy for drug novelty because drug projects that receive this designation are recognized by the FDA as having the potential to "*fill an unmet medical need*" or "*demonstrate substantial improvement over available therapy*."[20] As such, we classify a drug project as having "launched as a novel drug" if it launched in the U.S. after receiving an ERD.[21]

13. The Deals Data tracks M&As in the U.S. between 1995 and 2024, including the identities of acquirer and target firms and the date of completion of each deal.[22] We use this information to match the target firms in the Deals Data with firms involved in the development of drug projects in the Drug Development Data. This allows us to identify whether a drug project changed ownership during its development.[23] We find that 1,144 drug projects (3.5%) were acquired during development, whereas 31,955 (96.5%) were never acquired during their development.[24]

14. We use the combined dataset to classify firms as either large or small. Our primary measure of firm size defines a firm as "large" if it has launched at least one drug in the past, and "small" otherwise.[25] Intuitively, firms that have launched at least one drug are more likely to have obtained a steady revenue stream and accumulated expertise in late-stage development, regulatory approval, and commercialization. Thus, these "large" firms can share their resources with "small" target firms that have yet to bring drugs to market.

15. The combined dataset includes 435 drug projects originated by small firms that were then acquired by a large firm, and 424 drug projects originated by small firms that were then acquired by another small firm.[26] As further explained below, we use these differences in the type of acquiring firm to study the hypothesized mechanism through which M&As can impact drug launches, namely, by providing small firms with resources to bring pipeline drug projects to market.

IV. Acquired drug projects are significantly more likely to launch and to launch as novel drugs compared to non-acquired drug projects

16. We use the data described in Section III to analyze the relationship between M&As and innovation by comparing drug launches between acquired and non-acquired drug projects. We define acquired drug projects as those for which the originating firm was acquired by another firm while they were being developed (i.e., before they were launched or terminated). Then, we consider two measures of innovation: (i) whether a drug project was launched in the U.S., and (ii) whether a drug project was launched in the U.S. as a novel drug (i.e., launched after receiving an ERD).[27]

19 The FDA grants four types of ERDs: "Breakthrough Therapy," "Accelerated Approval," and "Priority Review" designations require potential for substantial improvements over available therapies, and "Fast Track" requires a potential to address unmet medical needs. *See* Table 1 in T. J. Hwang, J. S. Ross, K. N. Vokinger and A. S. Kesselheim, Association Between FDA and EMA Expedited Approval Programs and Therapeutic Value of New Medicines: Retrospective Cohort Study, *BMJ*, Vol. 371, 2020, pp. 1–8.

20 *See* FDA, Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, 12 June 2023, https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review.

21 We also explore an alternative definition of drug novelty in section VI.1. We note that the FDA refers to "novel" drugs as drugs whose active ingredient has never been approved or marketed in the U.S. *See* FDA, Novel Drug Approvals at FDA, 6 February 2025, https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda. In the main results of this article, we depart from the FDA's ingredient-based definition of drug novelty and consider the novelty of a drug from the standpoint of patients—i.e., whether it was recognized as having the potential to satisfy important patient needs through receipt of ERD. Nonetheless, most of the drugs that the FDA classifies as having a "*novel drug approval*" also received an ERD. For example, 74% of the FDA's "*novel drug approvals*" in 2021 received an ERD. *See* FDA, Advancing Health Through Innovation: New Drug Therapy Approvals 2021, January 2022, at 18, https://www.fda.gov/media/155227/download.

22 The data report 4,138 deals where the acquirer and target firms are both in the pharmaceutical industry. Of those 4,138 deals, 767 deals are successfully matched to target firms that are developing drug projects recorded in the Drug Development Data.

23 To do this, we construct a panel dataset tracking each drug project's owner in each year between 1995 and 2024. First, we identify the originator for each drug in our sample using the Drug Development Data. Then, using the Deals Data, we identify whether and when the originator was acquired by another firm. If an acquisition occurs, we update the drug project's current owner to reflect the change in company ownership. We continue with this process and update a drug's owner whenever its owner is acquired by another firm. To reliably identify changes in a drug project's ownership, we require a consistent firm identifier to track firms between and within datasets. We create this identifier by standardizing firm names across both datasets using text matching techniques and manual review (e.g., to account for changes in a firm's name). We further complement this process with extensive public research to confirm that the ownership structures that we derived are accurate.

24 Of the 31,955 drug projects that were never acquired during their development, 103 were acquired after being launched in the U.S. We consider these 103 drugs as "non-acquired" for the purposes of our analysis.

25 We explore alternative definitions of firm size in section VI.2.

26 In section V, we refer to these types of acquisitions as "large-small" and "small-small" acquisitions, respectively. The large-small acquisitions involve 435 drug projects initiated by 221 small firms and acquired by 74 unique large firms. The small-small acquisitions involve 424 drug projects initiated by 199 small firms and acquired by 187 unique small firms. These 859 drug projects make up 75% of the 1,144 acquired drug projects in our sample. In addition, there are 285 drug projects that were originated by large firms that were then acquired by another firm (239 acquired by another large firm and 46 acquired by a small firm). We classify the target and acquirer firms as small or large based on their drug portfolio at the time of the acquisition.

27 We focus on U.S. launches because our measure of whether a drug is novel is based on the FDA's designation.

17. Table 1 shows how these two measures of innovation vary between acquired and non-acquired drug projects. For each group, we calculate the likelihood of launch as the share of drug projects that are launched in the U.S. Then, we calculate the difference in likelihood of drug launch between these two groups and test whether it is statistically different from zero. We perform the same steps for the likelihood of drug projects launching as a novel drug.

18. Acquired drug projects are more likely to launch than non-acquired drug projects. As Table 1 shows, 7.7% of the acquired drug projects launched, compared to 3.9% of non-acquired drug projects. In other words, acquired drug projects are nearly twice as likely to launch as compared to non-acquired drug projects. This difference is not only large in magnitude, but also statistically significant.

19. Moreover, acquired drug projects are also more likely to launch as novel drugs (i.e., after receiving an ERD) than non-acquired projects. As shown in Table 1, among acquired drug projects, 3.2% launched as a novel drug, whereas 0.9% of non-acquired drug projects launched as a novel drug. In other words, acquired drug projects are more than three times as likely to launch as novel drugs than non-acquired drug projects. This large difference is also statistically significant.

Table 1. Difference in the share of drug projects that launched and share of drug projects that launched as a novel drug between acquired and non-acquired projects

	Acquired Drug Projects [A]	Non-Acquired Drug Projects [B]	Difference [B] – [A]
Share Launched	7.69 %	3.92 %	3.77 pp***
Share Launched as a Novel Drug	3.15%	0.94 %	2.20pp ***
Number of Drug Projects	1,144	31,955	—

20. While this evidence is supportive of M&As being positively associated with (novel) drug launches, acquired and non-acquired drug projects might differ in ways other than whether they undergo M&A and that can also affect the likelihood of launch. For example, projects that are acquired may be more likely to be further along in development.[28] However, projects that are further along in their development stage are also more likely to launch.[29] To account for factors like this, we adopt a regression framework that controls for drug project and firm characteristics that may affect both the likelihood of a drug launch and whether a drug project undergoes an M&A.

21. As shown in Table 2, the likelihood of launch remains higher for acquired drug projects as compared to non-acquired drug projects, even after controlling for these drug projects and firm characteristics. As discussed above, 3.92% of non-acquired projects launched. After controlling for drug project and originator firm characteristics, we find that acquired drug projects are 1.97 percentage points more likely to launch as compared to non-acquired drug projects, i.e., the likelihood of launch for acquired drug projects is 3.92 + 1.97 = 5.89%. This means that acquired drug projects are 1.5 times more likely to launch than non-acquired drug projects.[30]

22. Furthermore, the likelihood of launching as a novel drug (i.e., after receiving an ERD) is also higher for acquired vs. non-acquired projects after controlling for the same set of characteristics. Specifically, we find that 0.94% of non-acquired projects launched as novel drugs and that acquired drug projects are 1.64 percentage points more likely to launch as novel drugs than non-acquired ones. This means that 0.94 + 1.64 = 2.58% of acquired drug projects launched as novel drugs, which is approximately 2.7 times more likely than for non-acquired drug projects.[31] These results are all statistically significant.[32]

Table 1 notes:

[1] Drug projects are limited to those initiated between 1995 and 2024 and that experienced at least one development event after their initiation.

[2] Drug projects are classified as launching as a novel drug if they launched after receiving an ERD.

[3] Asterisks denote statistical significance of the difference. One asterisk (*) corresponds to significance at the 90% confidence level. Two asterisks (**) correspond to significance at the 95% confidence level. Three asterisks (***) correspond to significance at the 99% confidence level. These significance levels are based on a Welch's t-test.

28 For example, a study commissioned by the Department of Health and Human Services found that target firms' highest-value asset (excluding launched drugs) was most likely to be in Phase II or Phase III of clinical trials. *See* Department of Health and Human Services, Mergers and Acquisitions (M&As) in Pharmaceutical Markets: Associations with Market Concentration, Prices, Drug Quantity Sold, and Shortages, 8 January 2025, Table B-3, https://aspe.hhs.gov/sites/default/files/documents/ec5de77c-72cff3abf802b5e9c6cc8ae4/aspe-pharma-ma-report.pdf. Cunningham et al. (2021) find that drugs that are initiated earlier are more likely to be acquired, which they argue reflects that projects are often acquired several years into the drug development process. *See* Cunningham et al., *supra* note 5, at 670.

29 DiMasi et al. (2016) calculate that the likelihood that a drug project that enters clinical testing (i.e., Phase I) would be approved is 11.83%. The authors also find that there is a 59.52% likelihood of a drug project going from Phase I to Phase II. This means that a drug project entering Phase II has an 11.83/59.52 = 19.9% likelihood of approval. Using a similar logic, we can conclude that the likelihood of launch is even higher for drug projects in Phase III. *See* DiMasi et al., *supra* note 13, Figure 1.

30 This is calculated by using the likelihood of launch for small-small acquired drug projects (3.92%) and the difference in likelihood of launch between large-small and small-small acquired drug project from the regression results (1.97%). The likelihood of launch for large-small acquired drug project relative to small-small acquired drug projects is (3.92 + 1.97)/(3.92) = 1.5 times larger.

31 This is calculated by using the likelihood of launch as a novel drug for small-small acquired drug projects (0.94%) and the difference in likelihood of launch between large-small and small-small acquired drug project from the regression results (1.64%). This means that the likelihood of launch as a novel drug for large-small acquired drug project relative to small-small acquired drug projects is (0.94 + 1.64)/(0.94) = 2.74 times larger.

32 The statistical significance of the results does not change when using heteroskedasticity-robust standard errors. These results are qualitatively similar when using a logit probability model instead of a linear probability model. The logit regression model assumes that the likelihood of a drug launching is a logistic function of the factors that can influence it. This guarantees that the fitted values of the regression are always bounded between zero and one for any combination of the factors affecting the probability of launch. *See* J. M. Wooldridge, Multiple Regression Analysis with Qualitative Information, in *Introductory Econometrics: A Modern Approach*, 7th ed., Cengage Learning, Mason, 2009, pp. 220–261.

Table 2. Linear regression estimates of the difference in likelihood of launch and in likelihood of launch as a novel drug between acquired drug projects and non-acquired drug projects

	Launched	Launched as a Novel Drug
Difference between Acquired and Non-Acquired Projects	1.97 %***	1.64 %***
	(0.76)	(0.55)
Likelihood of Outcome for Non-Acquired Projects	3.92 %	0.94 %
Control Variables	✓	✓
Number of Observations	33,097	33,097
R^2 (adjusted)	0.05	0.03

V. The data support the hypothesized mechanism

23. Our finding that M&As are positively associated with (novel) drug launches can be explained by several possible economic mechanisms. For example, consistent with our hypothesized mechanism, when large firms acquire small firms, they provide these small firms with the resources necessary to bring pipeline drug projects to market. However, our finding is also consistent with alternative mechanisms, such as acquiring firms targeting the most promising and innovative projects when choosing which firms to acquire. As such, our results in Section IV do not allow us to distinguish which mechanisms might be at play.

24. In this section, we consider a test for the presence of our hypothesized mechanism. Specifically, we test for our hypothesized mechanism by comparing the likelihood of a drug launch between two types of M&As: those in which a large firm acquires a small firm ("large-small acquisitions") and those in which a small firm acquires another small firm ("small-small acquisitions").[33] A higher likelihood of launch for large-small acquisitions when compared to small-small acquisitions provides support for our hypothesized mechanism.

25. This comparison allows us to investigate whether there is empirical support for our hypothesized mechanism for two reasons. First, by construction, the hypothesized mechanism can only be at play in the large-small acquisitions. Hence, a higher likelihood of launch for large-small acquisitions relative to small-small acquisitions provides evidence consistent with our hypothesized mechanism. Second, in both large-small acquisitions and small-small acquisitions, the target company is a small firm. Thus, it is plausible that large-small acquired drug projects are more similar to small-small acquired drug projects than to non-acquired drug projects. A comparison of drug project groups that are more similar inherently limits the set of mechanisms that may explain observed differences in drug launches between the groups being compared.

26. In Table 3, we show the likelihood of launch for large-small acquisitions and small-small acquisitions. We find that small firms' drug projects that are acquired by large firms have a 9.2% likelihood of being launched. However, for those acquired by other small firms, the likelihood of being launched is only 3.3%. This large difference is also statistically significant. In other words, the likelihood for an acquired project to be launched is nearly three times higher for large-acquiring-small acquisitions than for small-acquiring-small acquisitions. As explained above, this is consistent with our hypothesized mechanism.

Table 2 notes:

[1] Drug projects are limited to those initiated between 1995 and 2025 and that experienced at least one development event after initiation.

[2] The table presents the estimates from two regression specifications. In the first specification, the dependent variable is an indicator for whether the drug project was launched. In the second specification, the dependent variable is an indicator for whether the drug project was launched as a novel drug (i.e., after receiving an ERD). In both specifications, the explanatory variable of interest is an indicator for whether the drug project was acquired. The coefficient estimate on this variable is estimated relative to the baseline category of non-acquired drug projects. We control for the following drug project characteristics: initiation year, disease groups (cardiovascular; respiratory; anti-infective; anti-cancer; neurological; dermatological; alimentary-metabolic; musculoskeletal; genitourinary including sex hormones; antiparasitic; blood and clotting; immunological; hormonal excluding sex hormones; sensory; or other), origin (chemical; biological; or natural product/not applicable), delivery route (injectable; oral; topical; inhaled; or other/not applicable), rare disease status, and U.S. originator. We also include an indicator for originator firms that attempted to develop more than 28 drug projects. This corresponds to the 95th percentile of firm size based on measuring firm size by the number of projects a firm has attempted to develop. See notes 49 and 50 for further details.

[3] Asterisks denote statistical significance of the difference. One asterisk (*) corresponds to significance at the 90% confidence level. Two asterisks (**) correspond to significance at the 95% confidence level. Three asterisks (***) correspond to significance at the 99% confidence level. Errors are clustered by the year of the drug project's initiation.

33 These two types of M&As make up 75% of the 1,144 acquired drug projects in our sample. *See* note 26.

27. To further test our hypothesis, we investigate whether the likelihood that a drug project launches as a novel drug varies by type of acquisition. Developing novel drugs can be more risky, costly, and time-intensive relative to developing other drugs.[34] As such, firms with more resources would be better able to overcome these hurdles and, therefore, be more likely to launch novel drugs. Under our hypothesized mechanism, large firms can provide small firms with resources to bring novel drugs to market. This means that if our hypothesized mechanism is at play, we would expect that acquired projects are more likely to launch as novel drugs for large-small acquisitions when compared to small-small acquisitions. Moreover, due to the challenges and complexities involved in developing novel drug projects, our hypothesized mechanism is likely to have a greater impact in the development of novel drug projects relative to other drug projects. This means we would expect to see a greater association between acquiring firm size and drug launch when looking at novel drug projects than when looking at drug projects overall.

Table 3. Difference in the share of drug projects that launched and share of drug projects that launched as a novel drug between small-small and large-small acquired drug projects

	Large–Small Acquisitions [A]	Small–Small Acquisitions [B]	Difference [A] – [B]
Share Launched	9.20 %	3.30 %	5.89 pp***
Share Launched as a Novel Drug	5.98 %	1.18 %	4.80 pp***
Number of Drug Projects	435	424	—

28. Our results, shown in Table 3, are consistent with our hypothesized mechanism. We find that the likelihood of launching as a novel drug (i.e., after receiving ERD) is much higher for large-small acquisitions relative to small-small acquisitions. Large-small acquired drug projects have approximately a 6.0% likelihood of launching as a novel drug. In contrast, small-small acquired drug projects have only approximately 1.2% likelihood of launching as a novel drug. This difference in launch rates is also statistically significant. This means that large-small acquired drug projects are more than five times more likely to launch as a novel drug than small-small acquired drug projects. In contrast, we discussed above that large-small acquired drug projects are 2.8 times more likely to launch than small-small acquired drug projects. Therefore, consistent with our hypothesized mechanism and the added complexities of developing novel drug projects, we find a greater positive association between acquiring firm size and drug launch when looking at novel drugs than when looking at all drugs overall.

29. We then investigate whether the observed differences can be explained by factors other than M&As. We follow a similar method as in Section IV and use a regression to account for a wide range of drug project characteristics.[35] Our results are shown in Panel A of Table 4. Our results remain after controlling for these drug project characteristics. We find that 3.3% of small-small acquired drug projects are launched and that 3.3 + 6.5 = 9.8% of large-small acquired drug projects are launched. This means that large-small acquired drug projects are three times more likely to launch than small-small acquired drug projects. Similarly, we find that 1.2% of small-small acquired drug projects and 1.2 + 4.8 = 6.0% of large-small acquired drugs are launched as novel drugs. This means that large-small acquired drugs are five times more likely to launch as novel drugs than small-small acquired drug projects.[36] These differences are statistically significant and similar to our findings in Table 3. Since five is greater than three, this means, as before, that we find a greater association between acquiring firm size and drug launch when looking at novel drug projects than when looking at all drug projects overall.

Table 3 notes:

[1] Drug projects are limited to those initiated between 1995 and 2024, that experienced at least one development event after initiation, and that were owned by small firms that were then acquired by another firm.

[2] Drug projects are classified as launching as a novel drug if they launched after receiving an ERD.

[3] A large-small (small-small) acquisition is where a large (small) firm acquires a small firm. A firm is defined as "large" if it launched at least one drug by the time of acquisition and "small" otherwise.

[4] Asterisks denote statistical significance of the difference. One asterisk (*) corresponds to significance at the 90% confidence level. Two asterisks (**) correspond to significance at the 95% confidence level. Three asterisks (***) correspond to significance at the 99% confidence level. These significance levels are based on a Welch's t-test.

34 *See* note 16.

35 We include the same set of controls as the regressions in Section IV, except for the firm size indicator. This is because our classification of M&As by size of the target and acquirer firms already accounts for the differences in firm sizes.

36 This is calculated by using the likelihood of launch for small-small acquired drug projects (3.30%) and the difference in likelihood of launch between large-small and small-small acquired drug projects from the regression results (6.47%). The likelihood of launch for large-small acquired drug projects relative to small-small acquired drug projects is (3.30 + 6.47)/(3.30) = 2.96 times larger. A similar calculation is used for the likelihood of launching as a novel drug, i.e., the relative likelihood is (1.18 + 4.79)/(1.18) = 5.06 times larger.

Table 4. Linear regression estimates of the difference in likelihood of launch and in likelihood of launch as a novel drug between large-small acquired drug projects and small-small acquired drug projects

	Panel A – All Acquired Projects – Launched	Panel A – All Acquired Projects – Launched as a Novel Drug	Panel B – Projects Acquired Within Three Years of Initiation – Launched	Panel B – Projects Acquired Within Three Years of Initiation – Launched as a Novel Drug
Difference between Large–Small Acquired and Small–Small Acquired Projects	6.47%***	4.79%***	4.11%*	4.13 %***
	(1.56)	(1.25)	(2.17)	(1.6)
Likelihood of Outcome for Small–Small Acquired Projects	3.3 %	1.18 %	2.94 %	0.84 %
Age at Acquisition	✓	✓	—	—
Other Control Variables	✓	✓	✓	✓
Number of Observations	1,144	1,144	581	581
R^2 (adjusted)	0.11	0.11	0.18	0.16

30. Finally, we evaluate whether an alternative mechanism could explain our results. We assess whether large firms could be systematically acquiring different types of drug projects as compared to small firms. For example, it is possible that large firms are better at identifying promising drug projects and are more likely than small firms to acquire these promising projects, thereby explaining the higher likelihood of launch in the acquisitions by large firms. To mitigate this concern, we repeat our analysis but restricting attention to drug projects where this alternative mechanism is unlikely to be present. That is, we analyze drug projects that are acquired during the early stages of their development cycle. It is often difficult for firms to know whether an early-stage drug project is likely to be successful or not, and thus differences in firms' ability to selectively target promising projects may not be a factor at this stage.[37] We repeat our regression analysis, but restrict attention to drugs that are acquired within three years from initiation.[38] These results are shown in Panel B of Table 4. We find that, among this sample of acquired drugs, 2.94% of small-small acquired drug projects and

Table 4 notes:

[1] In Panel A, drug projects are limited to those initiated between 1995 and 2024, that experienced at least one development event after initiation, and that were acquired by another firm. In Panel B, drug projects are further limited to those that were acquired within three years of initiation.

[2] Within each panel, the table presents the estimates from two regression specifications. In the first specification, the dependent variable is an indicator for whether the drug project was launched. In the second specification, the dependent variable is an indicator for whether the drug project was launched as a novel drug (i.e., after receiving an ERD). In both specifications, the explanatory variable of interest is an indicator for whether the drug project was owned by a small firm and then acquired by a large firm. The coefficient estimate on this variable is estimated relative to the baseline category of drug projects that were owned by a small firm and then acquired by another small firm. We include controls for indicators for other categories of acquisitions (i.e., large firm acquired by large firm and large firm acquired by small firm). We control for the following drug project characteristics: initiation year, disease groups (cardiovascular; respiratory; anti-infective; anti-cancer; neurological; dermatological; alimentary-metabolic; musculoskeletal; genitourinary including sex hormones; antiparasitic; blood and clotting; immunological; hormonal excluding sex hormones; sensory; or other), origin (chemical; biological; or natural product/not applicable), delivery route (injectable; oral; topical; inhaled; or other/not applicable), rare disease status, and U.S. originator. In Panel A, we also control for the drug project's age at acquisition (grouped into the following categories relative to initiation year: less than 2 years; between 2–3 years; between 4–6 years; or more than 6 years after initiation).

[3] A large-small (small-small) acquisition is where a large (small) firm acquires a small firm. A firm is defined as "large" if it launched at least one drug by the time of acquisition and "small" otherwise.

[4] Asterisks denote statistical significance of the difference. One asterisk (*) corresponds to significance at the 90% confidence level. Two asterisks (**) correspond to significance at the 95% confidence level. Three asterisks (***) correspond to significance at the 99% confidence level. Errors are clustered by the year of the drug project's initiation.

37 Many drugs that show promise in earlier stages are not successful in later stages of development due to safety and efficacy concerns. In many cases, it is difficult for firms to accurately gauge the likelihood of launch when a drug project is in early stages of development. *See* T. J. Hwang, D. Carpenter, J. C. Lauffenburger, B. Wang, J. M. Franklin and A. S. Kesselheim, Failure of Investigational Drugs in Late-Stage Clinical Development and Publication of Trial Results, *JAMA Internal Medicine*, Vol. 176, No. 12, 2016, pp. 1826–1833. If it is difficult for all firms to know which early-stage drug projects will launch, then we would be less concerned that large firms are better able (relative to small firms) to identify and acquire promising drug projects in the early stages of development.

38 Restricting the sample to the first three years should capture drug projects in early stages of development (i.e., drugs in Phase I and Phase II clinical trials). Wong et al. (2019) find that a "*typical trial takes a median time of 1.61, 2.94, and 3.84 years to complete Phase 1, Phase 2, and Phase 3, respectively*." *See* C. H. Wong, K. W. Siah and A. W. Lo, Estimation of Clinical Trial Success Rates and Related Parameters, *Biostatistics*, Vol. 20, No. 2, 2019, pp. 273–286, Supplemental material, at 19; FDA, Step 3: Clinical Research, 4 January 2018, https://www.fda.gov/patients/drug-development-process/step-3-clinical-research. Similarly, Brown et al. (2022) find that the median time from first-in-human clinical studies until marketing approval by the FDA was 8.3 years for "innovative" drugs (i.e., drugs with a new molecular entity or new active moiety). *See* D. G. Brown, H. J. Wobst, A. Kapoor, L. A. Kenna and N. Southall, Clinical Development Times for Innovative Drugs, *Nature Reviews Drug Discovery*, Vol. 21, No. 11, 2022, pp. 793–794. Our results also hold when changing this cut-off to four years or two years. *See* Table A.1 in the Appendix.

2.94 + 4.11 = 7.1% of large-small acquired drug projects are launched. This means that, relative to small-small acquisitions, drug projects that undergo large-small acquisitions are 2.4 times more likely to launch.[39] We also find that only 0.84% of small-small acquired drug projects and 0.84 + 4.13 = 5.0% of large-small acquisitions launch as novel drugs. This means that large-small acquired projects are 5.9 times more likely to launch as novel drugs than small-small acquired projects.[40] These differences are statistically significant as well.

31. Our results offer support for the hypothesized economic mechanism that large firms provide small target firms with resources to bring drug projects to market, and thus that M&As positively impact pharmaceutical innovation. Our findings suggest that the increased likelihood of drug launch, particularly novel drug launch, for acquired versus non-acquired projects may be explained, at least in part, by the hypothesized mechanism.

VI. Robustness checks

32. In this section, we show that our results are robust to using different measures of drug novelty and firm size.

1. Alternative measures of drug novelty

33. In Sections IV and V, we measure drug novelty by considering whether a drug project received an ERD from the FDA. As described above, such a designation is granted to drugs that the FDA deems to have the potential to "*fill an unmet medical need*" or "*demonstrate substantial improvement over available therapy*."[41] However, there may be other ways to measure drug novelty, depending on what data the researcher has available. In this section, we investigate whether our results are robust to an alternative measure of drug novelty that we can obtain from our dataset.

34. As an alternative measure of drug novelty, we consider whether a drug has a new "mechanism of action" (MoA)—a new way in which the drug "*produces an effect in the body*."[42] Drugs with new MoAs can be valuable to patients, as they offer new (and potentially more effective) ways to combat diseases.[43] Indeed, this measure of novelty has been recognized and used in prior academic literature.[44]

35. Using the MoA information in our dataset, we classify a drug as novel if it is the first drug in our sample to be launched with a given MoA.[45] We repeat our regression analyses from Sections IV and V using this alternative measure of novelty and find that our results continue to hold. Specifically, we find that relative to non-acquired drug projects, acquired drug projects are 1.6 times more likely to launch with a new MoA (this result is statistically significant).[46] Furthermore, we find that relative to small-small acquired drug projects, large-small acquired projects are nearly 24 times more likely to launch with a new MoA (this result is also statistically significant).[47] The substantially higher likelihood of launch with a new MoA for large-small acquired drug projects compared to small-small acquired drug projects is further evidence in support of our hypothesized mechanism.

2. Alternative measures of firm size

36. We also investigate whether our results are robust to alternative measures of firm size. Our results in Section V define a firm as "large" if it launched at least one drug. This is relevant for studying our mechanism of interest—a firm that has already successfully brought drug projects to market can provide valuable resources (e.g., financial resources, late-stage development expertise) to a firm that has not. However, our definition of "large" may not fully capture the extent of a firm's financial resources, infrastructure, staffing capacity, and other expertise in the pharmaceutical industry.[48]

37. As a robustness check, for each firm that underwent an M&A, we develop a measure of firm size that depends on the number of drug projects a firm has ever attempted

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39 This is calculated by using the likelihood of launch for small-small acquired drug projects (2.94%) and the difference in likelihood of launch between large-small and small-small acquired drug projects from the regression results (4.11%). The likelihood of launch for large-small acquired drug projects relative to small-small acquired drug projects is (4.11 + 2.94)/(2.94) = 2.40 times larger.

40 A similar calculation to the one described in note 39 is used for the likelihood of launching as a novel drug, i.e., the relative likelihood is (4.13 + 0.84)/(0.84) = 5.92 times larger.

41 *See* FDA, Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, 12 June 2023, https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review.

42 *See* National Cancer Institute, Mechanism of Action, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mechanism-of-action; Nature Portfolio, Mechanism of Action Articles from Across Nature Portfolio, https://www.nature.com/subjects/mechanism-of-action.

43 For example, Cardona et al. (2025) note that "[i]*ntroducing antibiotics with a new MoA is crucial for prolonging the effectiveness of the antibiotic arsenal. A novel MoA can bypass existing resistance mechanisms, making it harder for bacteria to survive and proliferate. This is particularly important in slowing down the emergence of resistance, thus extending the useful life of new antibiotics*." *See* S. T. Cardona, A. S. M. Zisanur Rahman and J. Novomisky Nechcoff, Innovative Perspectives on the Discovery of Small Molecule Antibiotics, *NPJ Antimicrobials and Resistance*, Vol. 3, No. 19, 2025, pp. 1–11, at 6.

44 *See* D. Dranove, C. Garthwaite and M. Hermosilla, Does consumer demand pull scientifically novel drug innovation?, *RAND Journal of Economics*, Vol. 53, No. 3, 2022, pp. 590–638; Levine et al., *supra* note 9; R. Kneller, The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs, *Nature Reviews Drug Discovery*, Vol. 9, No. 11, 2010, pp. 867–882.

45 We follow an approach similar to the methodology employed by Dranove et al., *supra* note 44. To identify each drug's MoA, we process the recorded MoA information in our data. We identify the key terms of each MoA (e.g., by removing suffixes) to identify distinct MoAs. For drugs with multiple MoAs, we consider the combination of MoAs to be a distinct MoA.

46 *See* Table A.2 in the Appendix. The relative likelihood is calculated as (0.81 + 1.43)/1.43 = 1.57.

47 *See* Table A.3 in the Appendix. The relative likelihood is calculated as (5.391 + 0.236)/0.236 = 23.84.

48 For example, based on our classification of firm size that we use in Section V, a firm with only one launched drug and no other drugs in its portfolio is "large," but a firm with, say, 30 drugs in its portfolio, none of which are launched, would be considered "small."

to develop by the time of the acquisition.[49] One might expect that a firm that has attempted to develop many drug projects is likely to have greater resources (e.g., expertise, staffing capacity) at its disposal than a firm that attempted to develop fewer drug projects.

38. We find that 90% of firms in our dataset have attempted to develop fewer than 17 drug projects.[50] For each M&A in our data, we define the firms involved as "large" if they attempted to develop at least 17 projects leading up to the acquisition, and as "small" otherwise. Using this definition, we find that relative to small-small acquired drug projects, large-small acquired drug projects are nearly twice as likely to launch and over three times more likely to launch as a novel drug.[51] Both of these results are statistically significant.

39. We further investigate if our results are robust to different cut-offs for the number of attempted drug projects used to classify a firm as large or small. In particular, we investigate how our results change if, instead of 17 projects (90th percentile), we set this number equal to 11, 28, or 83 projects—respectively, the 80th, 95th, and 99th percentiles for the number of drug projects attempted by firms in our data. We find that our results are robust to each of these cut-offs. Relative to small-small acquired drug projects, large-small acquired drug projects are more likely to launch and more likely to launch as novel drugs.[52] All of these results are statistically significant.[53]

VII. Discussion of results and avenues for future research

40. The economics literature on the impact of M&As on pharmaceutical innovation has largely been theoretical, and the few empirical studies have mostly focused on innovation outcomes that do not directly impact patients. In this study, we empirically investigate the association between M&As and two measures of innovation that directly impact patients: the likelihood of drug launch overall and the likelihood of novel drug launch. Our contribution to the economics literature is twofold. First, we find a positive association between M&As and our measures of pharmaceutical innovation. Second, we show that our empirical results are consistent with our hypothesized mechanism, namely, that M&As can stimulate pharmaceutical innovation through large acquiring firms providing resources to small target firms that help bring pipeline drug projects to market.

41. One topic for future research is to better understand our hypothesized mechanism. That is, it would be important to investigate the types of resources large firms provide to small firms through M&As, and which resource type is more crucial for stimulating innovation. For example, is it financial resources or prior experience with late-stage drug development that is more important in affecting the likelihood of drug launches? Furthermore, it would be helpful to investigate how and to what extent each of the distinct resources affects the likelihood of drug launches, and novel drug launches in particular.

42. Another topic for future research is to investigate whether large firms play a role in converting small firms' drug projects into novel projects through M&As. That is, large firms may be better than small firms at changing the properties of a drug project or discovering alternative uses for a drug in a way that makes the drug project novel.[54] In this way, M&As may promote the launch of novel drugs not only through the resources that large firms can provide to small firms to develop their existing technology, but also through the ability of large firms to identify important unmet medical needs that may be met with the acquired drug technologies and steer acquired drug projects towards them.

43. Finally, future research could also investigate if large-small acquisitions improve the market performance of acquired drugs that launch relative to small-small acquisitions. For example, large firms typically also have better distribution networks and marketing capabilities than small firms,[55] which could help the acquired company increase the patient and physician reach of the acquired drug. Such analysis can provide a fuller picture of the effects of M&As on consumer welfare by investigating not only the impact of M&As on the likelihood of (novel) drug launch, but also the impact of M&As on subsequent patient demand for the acquired drugs that launch. ■

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49 To construct this measure, we calculate the number of drug projects that each firm in our data has ever attempted to develop from the start of our data until the end of our data.

50 The number of drug projects used to define firm size is limited to the projects in the Drug Development Data, which only includes drug projects initiated after 1969 and has limited coverage on drug projects initiated before 1995. However, this is not a substantial data limitation because we are only interested in a measure of relative firm size rather than in knowing the precise number of drug projects per firm.

51 *See* Table A.4 in the Appendix. These are calculated as (3.92 + 4.51)/4.51 = 1.9 and (3.2 + 1.41)/1.41 = 3.3.

52 *See* Table A.4 in the Appendix.

53 We also tested the robustness of our results when changing the definition of "large" firms based on the number of launched drugs. In our main specification, we categorize a firm as "large" if it launched at least one drug by the time of acquisition. If we define large firms as those that launched at least five drugs, we find that large-small acquired drug projects are 2.4 times more likely to launch overall and 3.5 times more likely to launch as novel drugs than small-small acquired drug projects, respectively. If we instead define large firms as those that launched at least 10 drugs, we find that large-small acquired drug projects are 2.0 times as likely to launch and 2.1 times more likely to launch as novel drugs than small-small acquired drug projects, respectively. All of these results are statistically significant.

54 *See* Y. Cha, T. Erez, I. J. Reynolds, D. Kumar, J. Ross, G. Koytiger, R. Kusko, B. Zeskind, S. Risso, E. Kagan, S. Papapetropoulos, I. Grossman and D. Laifenfeld, Drug Repurposing from the Perspective of Pharmaceutical Companies, *British Journal of Pharmacology*, Vol. 175, No. 2, 2018, pp. 168–180, at 169 ("[L]*arger pharmaceutical companies may be more focused on LCM* [life cycle management] *activities of a specific product or molecule, which is often done as part of the late-stage development of the product or post-marketing. For these reasons, partnerships between smaller repurposing technology companies and larger pharmaceutical companies, when effectively executed, represent an attractive means to combine advanced repurposing capabilities with deep expertise in drug development*").

55 *See* Congressional Budget Office, Research and Development in the Pharmaceutical Industry, April 2021, at 4 ("*They* [large drug companies] *also have readier access to markets through established drug distribution networks and relationships with buyers*"); R. Bansal, R. De Backer and V. Ranade, What's Behind the Pharmaceutical Sector's M&A Push, McKinsey & Company, October 2018, at 3.

Appendix

Table A.1. Robustness: restricting the sample to drug projects that were acquired within two or four years after initiation for regression analysis within acquired drug projects

	Panel A – Projects Acquired Within Two Years of Initiation – Launched	Panel A – Projects Acquired Within Two Years of Initiation – Launched as a Novel Drug	Panel B – Projects Acquired Within Four Years of Initiation – Launched	Panel B – Projects Acquired Within Four Years of Initiation – Launched as a Novel Drug
Difference between Large–Small Acquired and Small–Small Acquired Projects	2.18%	3.15 %*	4.03 %**	3.86 %***
	(2.27)	(1.65)	(1.88)	(1.42)
Likelihood of Outcome for Small–Small Acquired Projects	3.17 %	1.06 %	2.96 %	0.74 %
Other Control Variables	✓	✓	✓	✓
Number of Observations	445	445	691	691
R^2 (adjusted)	0.19	0.17	0.16	0.14

Notes:

[1] In Panel A, drug projects are limited to those initiated between 1995 and 2024, that experienced at least one development event after initiation, and that were acquired by another firm within two years of the drug project's initiation. In Panel B, drug projects are instead limited to those that were acquired within four years of initiation.

[2] Within each panel, the table presents the estimates from two regression specifications. In the first specification, the dependent variable is an indicator for whether the drug project was launched. In the second specification, the dependent variable is an indicator for whether the drug project was launched as a novel drug (i.e., after receiving an ERD). In both specifications, the explanatory variable of interest is an indicator for whether the drug project was owned by a small firm and then acquired by a large firm. The coefficient estimate on this variable is estimated relative to the baseline category of drug projects that were owned by a small firm and then acquired by another small firm. We include controls for indicators for other categories of acquisitions (i.e., large firm acquired by large firm and large firm acquired by small firm). We control for the following drug project characteristics: initiation year, disease groups (cardiovascular; respiratory; anti-infective; anti-cancer; neurological; dermatological; alimentary-metabolic; musculoskeletal; genitourinary including sex hormones; antiparasitic; blood and clotting; immunological; hormonal excluding sex hormones; sensory; or other), origin (chemical; biological; or natural product/not applicable), delivery route (injectable; oral; topical; inhaled; or other/not applicable), rare disease status, and U.S. originator.

[3] A large-small (small-small) acquisition is where a large (small) firm acquires a small firm. A firm is defined as "large" if it launched at least one drug by the time of acquisition and "small" otherwise.

[4] Asterisks denote statistical significance of the difference. One asterisk (*) corresponds to significance at the 90% confidence level. Two asterisks (**) correspond to significance at the 95% confidence level. Three asterisks (***) correspond to significance at the 99% confidence level. Errors are clustered by the year of the drug project's initiation.

Table A.2. Robustness: using an alternative measure of drug novelty for regression analysis between acquired and non-acquired drug projects

	Launched with new MoA
Difference between Acquired and Non-Acquired Projects	0.81%**
	(0.4)
Likelihood of Outcome for Non-Acquired Projects	1.43 %
Control Variables	✓
Number of Observations	33,097
R^2 (adjusted)	0.03

Notes:

[1] Drug projects are limited to those initiated between 1995 and 2025 and that experienced at least one development event after initiation.

[2] The table presents the estimates from one regression specification. In this specification, the dependent variable is an indicator for whether the drug project was launched with a new mechanism of action (MoA). The explanatory variable of interest is an indicator for whether the drug project was acquired. The coefficient estimate on this variable is estimated relative to the baseline category of non-acquired drug projects. We control for the following drug project characteristics: initiation year, disease groups (cardiovascular; respiratory; anti-infective; anti-cancer; neurological; dermatological; alimentary-metabolic; musculoskeletal; genitourinary including sex hormones; antiparasitic; blood and clotting; immunological; hormonal excluding sex hormones; sensory; or other), origin (chemical; biological; or natural product/not applicable), delivery route (injectable; oral; topical; inhaled; or other/not applicable), rare disease status, and U.S. originator. We also include an indicator for originator firms that attempted to develop more than 28 drug projects. This corresponds to the 95th percentile of firm size based on measuring firm size by the number of projects a firm has attempted to develop. See notes 49 and 50 for further details.

[3] A drug project is classified as launching with a new MoA if it is the first drug project in our sample to be launched in the U.S. with a given MoA. To identify each drug's MoA, we process the recorded MoA information in our data. We identify the key terms of each MoA (e.g., by removing suffixes, Roman numerals, Greek letters, etc.) to identify distinct MoAs. For drugs with multiple MoAs, we consider the combination of MoAs to be a distinct MoA.

[4] Asterisks denote statistical significance of the difference. One asterisk (*) corresponds to significance at the 90% confidence level. Two asterisks (**) correspond to significance at the 95% confidence level. Three asterisks (***) correspond to significance at the 99% confidence level. Errors are clustered by the year of the drug project's initiation.

Table A.3. Robustness: using an alternative measure of novelty for regression analysis within acquired drug projects

	Launched with new MoA
Difference between Large–Small Acquired and Small–Small Acquired Projects	5.39%***
	(1.4)
Likelihood of Outcome for Small–Small Acquired Projects	0.24 %
Control Variables	✓
Number of Observations	1,144
R^2 (adjusted)	0.11

Notes:

[1] Drug projects are limited to those initiated between 1995 and 2024, that experienced at least one development event after initiation, and that were acquired by another firm.

[2] The table presents the estimates from one regression specification. In this specification, the dependent variable is an indicator for whether the drug project was launched with a new mechanism of action (MoA). The explanatory variable of interest is an indicator for whether the drug project was owned by a small firm and then acquired by a large firm. The coefficient estimate on this variable is estimated relative to the baseline category of drug projects that were owned by a small firm and then acquired by another small firm. We include controls for indicators for other categories of acquisitions (i.e., large firm acquired by large firm and large firm acquired by small firm). We control for the following drug project characteristics: initiation year, disease groups (cardiovascular; respiratory; anti-infective; anti-cancer; neurological; dermatological; alimentary-metabolic; musculoskeletal; genitourinary including sex hormones; antiparasitic; blood and clotting; immunological; hormonal excluding sex hormones; sensory; or other), origin (chemical; biological; or natural product/not applicable), delivery route (injectable; oral; topical; inhaled; or other/not applicable), rare disease status, and U.S. originator. We also control for the drug project's age at acquisition (grouped into the following categories relative to initiation year: less than 2 years; between 2–3 years; between 4–6 years; or more than 6 years after initiation).

[3] A drug project is classified as launching with a new MoA if it is the first drug project in our sample to be launched in the U.S. with a given MoA. To identify each drug's MoA, we process the recorded MoA information in our data. We identify the key terms of each MoA (e.g., by removing suffixes, Roman numerals, Greek letters, etc.) to identify distinct MoAs. For drugs with multiple MoAs, we consider the combination of MoAs to be a distinct MoA.

[4] A large-small (small-small) acquisition is where a large (small) firm acquires a small firm. A firm is defined as "large" if it launched at least one drug by the time of acquisition and "small" otherwise.

[5] Asterisks denote statistical significance of the difference. One asterisk (*) corresponds to significance at the 90% confidence level. Two asterisks (**) correspond to significance at the 95% confidence level. Three asterisks (***) correspond to significance at the 99% confidence level. Errors are clustered by the year of the drug project's initiation.

Table A.4. Robustness: using alternative definitions of firm size for regression analysis within acquired drug projects

	Panel A – Large firms above 80th percentile of size distribution – Launched	Panel A – Large firms above 80th percentile of size distribution – Launched as a Novel Drug	Panel B – Large firms above 90th percentile of size distribution – Launched	Panel B – Large firms above 90th percentile of size distribution – Launched as a Novel Drug
Difference between Large–Small Acquired and Small–Small Acquired Projects	3.55 %*	2.61 %**	3.92 %**	3.2 %**
	(2.06)	(1.33)	(2.19)	(1.4)
Likelihood of Outcome for Small–Small Acquired Projects	5.00 %	1.92 %	4.51 %	1.41 %
Control Variables	✓	✓	✓	✓
Number of Observations	1,144	1,144	1,144	1,144
R^2 (adjusted)	0.10	0.10	0.10	0.10

	Panel C – Large firms above 95th percentile of size distribution – Launched	Panel C – Large firms above 95th percentile of size distribution – Launched as a Novel Drug	Panel D – Large firms above 99th percentile of size distribution – Launched	Panel D – Large firms above 99th percentile of size distribution – Launched as a Novel Drug
Difference between Large–Small Acquired and Small–Small Acquired Projects	4.17%***	3.1 %**	6.91 %***	4.01 %***
	(2.06)	(1.25)	(1.61)	(1.15)
Likelihood of Outcome for Small–Small Acquired Projects	4.66 %	1.77 %	4.83 %	1.50 %
Control Variables	✓	✓	✓	✓
Number of Observations	1,144	1,144	1,144	1,144
R^2 (adjusted)	0.10	0.10	0.11	0.10

Notes:

[1] Drug projects are limited to those initiated between 1995 and 2024, that experienced at least one development event after initiation, and that were acquired by another firm.

[2] Within each panel, the table presents the estimates from two regression specifications. In the first specification, the dependent variable is an indicator for whether the drug project was launched. In the second specification, the dependent variable is an indicator for whether the drug project was launched as a novel drug (i.e., after receiving an ERD). In both specifications, the explanatory variable of interest is an indicator for whether the drug project was owned by a small firm and then acquired by a large firm. The coefficient estimate on this variable is estimated relative to the baseline category of drug projects that were owned by a small firm and then acquired by another small firm. We include controls for indicators for other categories of acquisitions (i.e., large firm acquired by large firm and large firm acquired by small firm). We control for the following drug project characteristics: initiation year, disease groups (cardiovascular; respiratory; anti-infective; anti-cancer; neurological; dermatological; alimentary-metabolic; musculoskeletal; genitourinary including sex hormones; antiparasitic; blood and clotting; immunological; hormonal excluding sex hormones; sensory; or other), origin (chemical; biological; or natural product/not applicable), delivery route (injectable; oral; topical; inhaled; or other/not applicable), rare disease status, and U.S. originator. We also control for the drug project's age at acquisition (grouped into the following categories relative to initiation year: less than 2 years; between 2–3 years; between 4–6 years; or more than 6 years after initiation).

[3] A large-small (small-small) acquisition is where a large (small) firm acquires a small firm. Each panel reports estimates based on alternative definitions of "large" and "small" firms. In Panel A, a firm is defined as "large" if it has attempted to develop more than 11 drug projects by the time of the acquisition. This corresponds to the 80th percentile of the distribution of firm size based on the number of projects that they ever attempted to develop. In Panel B, the cutoff is set at 17 drug projects (the 90th percentile). In Panel C, the cutoff is set at 28 drug projects (the 95th percentile). In Panel D, the cutoff is set at 83 drug projects (the 99th percentile).

[4] Asterisks denote statistical significance of the difference. One asterisk (*) corresponds to significance at the 90% confidence level. Two asterisks (**) correspond to significance at the 95% confidence level. Three asterisks (***) correspond to significance at the 99% confidence level. Errors are clustered by the year of the drug project's initiation.