Private Equity Report

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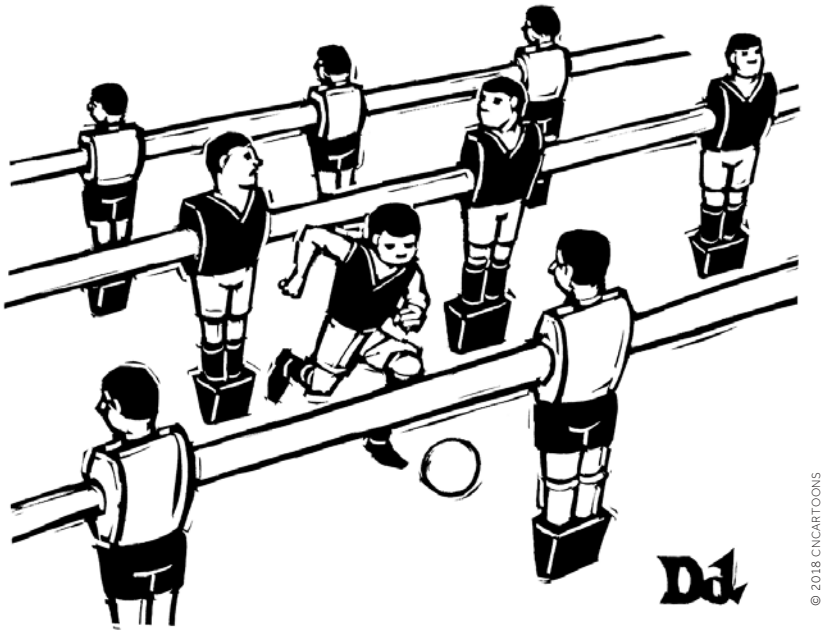

"You can always tell which guys aren't trapped in long-term contracts."

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From the Editors

With record amounts of dry powder chasing a finite number of deals and continued pressure from investors for returns, private equity funds are facing a highly competitive market on all fronts. General partners are responding by finding innovative ways of offering attractive terms at auction, meeting investor needs for liquidity and investing further in high-growth industries.

This issue of the Private Equity Report explores several current developments along these lines that general partners, investors and management will find of interest:

Liquidity without Exits: Incentivizing Management for the Long Term

With long-dated funds growing in popularity and direct investing by alternative capital pools increasingly common, sponsors are developing new long-term incentive plans to meet the needs of all stakeholders.

Introducing Full Equity Backstops to the PE Toolkit

As auction dynamics continue to place high priority on speed and

Continued on page 2

Private Equity Report
Spring 2018
Volume 18, Number 1

certainty of closing, offering to fund the total purchase price with a full equity backstop can prove useful for sponsors looking to differentiate themselves.

GP-Led Restructurings: Shaking up the World of Private Funds

GP-Led restructurings have long been associated with underperforming "end of life" assets, but in recent years, GPs have been turning to restructurings to actively manage their fund's portfolio while providing their investors with a liquidity option.

Life Sciences Investing under Trump: Food and Drug Administration Developments

FDA Commissioner Scott Gottlieb, M.D., has launched sweeping initiatives to accelerate innovation and lower regulatory burdens. Nonetheless, PE investors need to stay mindful of a complex regulatory environment and hot-button issues like opioids and pricing.

We hope you find these articles thought provoking and helpful as you structure your own strategies for this dynamic market.

The Editors

Liquidity without Exits: Incentivizing Management for the Long Term

"For long-term hold investments, it is important to consider providing other liquidity outlets so that equity and long-term incentive arrangements properly align management's interest with the interest of sponsors."

With the growth of long-dated funds and the rise of direct investing by alternative capital pools such as pension plans and family offices which may intend to hold portfolio investments for long, or indefinite, periods, the increasingly asked question is: How does such an investor motivate management with no exit in sight? For long-term hold investments, it is important to consider providing other liquidity outlets so that equity and long-term incentive arrangements properly align management's interest with the interest of sponsors. This article describes some alternative liquidity programs for sponsors' playbooks.

In Together, Out Together

Historically, direct investing was the domain of private equity funds with a finite life, which operate with plans to exit investments in three to five years. In order to align the interests of portfolio company management with those of the sponsor, management incentives are often linked to the equity of the company so that management and the sponsor are linked until the sponsor exits (*i.e.*, management and the sponsor both enter into and exit the investment together). Vesting conditions are typically intended to incentivize one or more of (i) employee retention (*e.g.*, continued service for three to five years), (ii) company performance over three to five years (*e.g.*, EBITDA, revenue, etc.) and (iii) sponsor investment return (*e.g.*, an exit in which the fund achieves a multiple of invested capital and/or IRR).

Management is obviously focused on how to monetize their equity awards. In the spirit of "in together, out together," management equity is generally illiquid until the sponsor has a realization event (*e.g.*, a sale of the company, a leveraged recap, or a special dividend). If an employee is fired or resigns before a realization event, the company and/or sponsor often have a right, but not an obligation, to repurchase the employee's vested equity at fair market value (or at the lower of fair market value and its original cost, if the employee is a bad leaver). While this may provide an employee with liquidity in connection with his or her termination, the employee has no assurance that the company or sponsor will exercise the right, and the employee may need to continue holding the award until a realization event. On the other hand, if a company frequently repurchases equity from departing employees, lack of another liquidity alternative may create a perverse incentive to leave.

Continued on page 4

Private Equity Report
Spring 2018
Volume 18, Number 1

Early Liquidity for Long-Term Holds

The market for private equity investing has diversified in recent years and includes players who buy companies with a longer term investment horizon. Such investors need to modify the typical management incentive playbook in order for it to actually incentivize. Members of management typically want to see the fruits of their labor within the reasonably foreseeable future, and if management does not see that "light at the end of the tunnel," alignment of management's and the sponsor's interests is unlikely, management may devalue the award, and the award may have reduced effectiveness inducing retention and performance.

> "Members of management typically want to see the fruits of their labor within the reasonably foreseeable future, and if management does not see that "light at the end of the tunnel," alignment of management's and the sponsor's interests is unlikely...."

Some investors who do not have specific exit horizons do not provide long-term incentives to management. But sponsors who wish to address these concerns may do so by providing forms of "early" liquidity for management equity through:

Special liquidity rights. A sponsor may permit members of management to sell their vested equity awards back to the company (before a termination of employment and before a sponsor exit) at predetermined times. Factors to bear in mind in utilizing such special put rights include:

- Making management comfortable that the methodology for determining the repurchase price is fair; and
- Ability of the business to generate or raise the funds necessary to fund the repurchase (and making sure there is room under any portfolio company debt agreement repurchase baskets). A separate limit on put rights may be advisable to prevent a "run on the bank" (*i.e.*, a significant drain on cash resources due to the exercise of put rights at the same time) or the loss of incentive if employees cash out 100% of their equity in a single sale.

Distribution rights. Distribution rights entitle the employee to receive in-service cash dividends and cash distributions on the employee's equity awards. Factors to consider with distribution rights include:

- Whether they should be granted on a stand-alone basis or in connection with other equity awards; and
- Whether they should be paid at the same time as distributions made to the company's other equity holders or upon vesting or settlement of the underlying awards to which such rights relate.

Internal market program. An internal market program allows employees to buy their equity interests directly from and sell their equity interests directly to one another.

- This allows employees to monetize their awards, while avoiding liability accounting that might otherwise apply to put rights in certain circumstances and at a time when company purchases are prohibited by financing covenants.
- However, this type of program requires participants with enough wealth and interest to fund purchases (which is a primary reason internal market programs are not typically used).

There are pros and cons to each of these alternatives, and care must be taken to structure a management incentive program for the relevant securities law, tax and accounting implications. Whichever alternative

Continued on page 5

Private Equity Report
Spring 2018
Volume 18, Number 1

a sponsor chooses, however, vesting conditions, such as time-based vesting to incentivize retention and performance-based vesting to incentivize performance (*e.g.*, EBITDA), could be used to align management's interest with the sponsor's interest.

Long-Term Cash Incentives

A well-designed long-term cash incentive program can be very useful in aligning management's interests with those of a sponsor who intends to hold a portfolio company for an indefinite period of time. Such a program could motivate employee performance, reward management for company growth and provide a counterbalance against short-term risks. A major "pro" of long-term cash incentives is the flexibility in design they afford. However, there are disadvantages as well—care must be taken to avoid or comply with Internal Revenue Code Section 409A and Section 457A, and a long-term incentive program is subject to liability accounting. Furthermore, long-term incentive programs can be complex and difficult to understand and communicate. Effective long-term incentive metrics should be as simple as possible (it is best if they are limited to three or fewer measures and are quantifiable and measurable) but also sufficient to focus management on the sponsor's business objectives and to incentivize management to achieve the desired results. Long-term incentives should be capable of factoring in changes to the company's business and structure but also incapable of inappropriate manipulation by management.

"Long-term incentives should be capable of factoring in changes to the company's business and structure but also incapable of inappropriate manipulation by management."

The Choice Is Yours

There is no objectively "right" or "wrong" incentive program for management of a portfolio investment that the sponsor does not anticipate exiting in the near future. A properly designed program should be tailored to each sponsor's needs. Most importantly, because management's incentive program is different from the financial sponsor's equity interests, there is added emphasis on ensuring that the program works with employee expectations. Therefore, in designing a management incentive program, an investor with a long-term investment horizon should carefully consider management's tolerance for complexity, how to make management comfortable with the new owners and how to sell the program to management. As noted above, there are a variety of alternatives to choose from, and an appropriate incentive program can be structured to meet the needs of both management and the financial sponsor.

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Introducing Full Equity Backstops to the PE Toolkit

"Agreeing to a full equity backstop can give a sponsor a leg up on other sponsor bidders and put the sponsor on equal footing with strategic buyers in the seller's consideration of deal certainty."

As competition for deals remains heated, full equity backstops have become a useful option for sponsors willing to be aggressive to distinguish themselves in auctions. Agreeing to a full equity backstop can give a sponsor a leg up on other sponsor bidders and put the sponsor on equal footing with strategic buyers in the seller's consideration of deal certainty. We saw an uptick in the use of full equity backstops in 2017 and expect that trend to continue in 2018. However, potentially having to fund the entire purchase price with equity raises a number of considerations.

Background

Under the traditional deal model, sponsors commit to fund a limited equity contribution in the event debt financing is available and guarantee payment of a reverse termination fee in the event debt financing is not available. In providing a full equity backstop, however, the sponsor commits to fund the full purchase price. Full equity backstops came to prominence with Vista's $4.2 billion take-private of TIBCO in 2014. Vista never intended to fully fund the transaction with equity (it secured debt financing commitments the day after the acquisition agreement was signed), but the additional closing certainty that its bid contained helped Vista win a hot auction. At the time, Vista's use of a full equity backstop in such a substantial deal raised eyebrows among practitioners. Although full equity backstops have become more common in the past few years, they remain most often seen in smaller- to middle-market deals.

Fund Restrictions

One gating item a sponsor should consider is whether its fund documents permit use of a full equity backstop for a given deal. Diversification limits can render full equity backstops more suitable for use in a sponsor's smaller deals. Fund documents do sometimes provide for higher concentration limits to the extent bridge equity is used in a deal. This provision can be useful in the context of a full equity backstop, since a sponsor will typically seek not to fund the entire purchase price with equity and, if forced to do so, would intend to refinance much of the equity with debt as quickly as possible following closing. These bridge provisions in fund documents raise numerous considerations, including how the bridge financing will be treated from a carried interest waterfall perspective, how the bridged amount will impact track record and IRR reporting and whether the bridge capital can be "recycled" for use in subsequent investments.

Continued on page 7

Private Equity Report
Spring 2018
Volume 18, Number 1

Fund-Level Debt as an Alternative

In a scenario in which a sponsor is not able to obtain debt commitments to support a full equity backstop, but a fund-level debt facility is available, that debt facility can be used to finance the "equity" required to be funded. A sponsor must consider whether there is sufficient capacity under the fund-level facility, how quickly the funds can be drawn and how long borrowings may remain outstanding. Fund-level debt facilities have become common among sizable sponsors. (For more on this, see https://www.debevoise.com/insights/publications/2017/07/fund-finance-focus-dont-neglect.)

Damages Caps

Although the seller will have the ability to seek specific performance of the sponsor's full equity backstop, the sponsor will typically seek a cap on a potential damages claim equal to an amount lower than the purchase price. Sponsors are often successful in obtaining these caps, which can be in the range of a traditional reverse termination fee or higher (*e.g.*, 10% or 20% of the purchase price). A principal rationale for imposing a cap on damages is to deter sellers from opting for a damages remedy for breach in lieu of specific performance.

> "With auction dynamics continuing to tilt in favor of sponsors who can distinguish their bids by providing speed and certainty of closing, we expect focus on full equity backstops to only increase."

Takeaways

With auction dynamics continuing to tilt in favor of sponsors who can distinguish their bids by providing speed and certainty of closing, we expect focus on full equity backstops to only increase. Sponsors who might consider agreeing to a full equity backstop in a future deal should become familiar with the technology, including the interplay with the sponsor's fund documents and any fund-level debt facility that may be in place.

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GP-Led Restructurings: Shaking up the World of Private Funds

"In recent years, we have increasingly seen healthy GPs use restructurings to actively manage their fund's portfolio while providing a liquidity option to their investors."

Once associated with zombie or "end-of-life" funds holding underperforming assets, GP-Led restructurings and other liquidity solutions are increasingly used by healthy GPs to actively manage their fund's portfolio and boost the fund-raising of their next fund while meeting the varying needs of different investors, some of whom may want liquidity while others may prefer to retain exposure to a fund's assets. As we predicted in our winter 2016 article, there has been a significant increase in the number of these transactions in both the US and Europe.[1] This article highlights techniques for achieving a successful fund restructuring with satisfactory outcomes for all stakeholders, in particular safely navigating through potential conflicts of interest.

From Zombie Funds to Active Portfolio Management

A few years ago, GP-Led fund restructurings were primarily associated with zombie or "end-of-life" funds with underperforming portfolios. In recent years, we have increasingly seen healthy GPs use restructurings to actively manage their fund's portfolio while providing a liquidity option to their investors. For example, Warburg Pincus sold last year a $1.2 billion portfolio of Asian investments from its 2012-vintage fund reportedly to reduce its exposure to the region. Some GPs have also used restructurings to boost the fundraising of their other funds. Both EQT's and BC Partners' fund restructurings last year are widely reported to have included a stapled commitment to their new funds.

Most GP-Led restructurings fall into one of three main categories:

Secondaries directs: The GP sells the fund's remaining assets to a secondary investor.

GP-Led LP tender offers: The GP presents an offer from a secondary investor to its existing LPs, who have the option to sell or stay in the fund. LP tender offers can take the form of a liquidity offering with no amendments to the fund terms (other than an extension of the fund's life) or entail a large or small renegotiation of the fund's terms.

"Asset deals" or fund recapitalisations: The assets of the fund are transferred to a new vehicle managed by the same GP and backed by a secondary investor, with existing LPs having the option to "cash out" or "roll over" their interests into the new vehicle.

Asset deals and LP tender offers may also involve a stapled commitment by the secondary buyer to the GP's next fund. Which of these techniques is most appropriate for a potential restructuring will depend on, among other factors, the LP constituency and the remaining assets in the portfolio.

Continued on page 9

1. *Private Equity Fund Restructurings: When End-of-Term Isn't the End,* The Private Equity Report, Winter 2016, Vol.16, No.1.

Private Equity Report
Spring 2018
Volume 18, Number 1

In general, the techniques of GP-Led restructurings are shared across the US and Europe, and both sides of the Atlantic have seen vigorous activity in recent years, although there are technical differences in structuring between the regions (such as the use of statutory mergers in the US).

Last year, GP-Led restructurings accounted for 24% of secondaries by deal volume (slightly up from 2016). 2018 is expected to be a strong year too, with Nordic Capital's restructuring of its 2008-vintage fund being one of the largest GP-Led restructurings ever completed.

Not all GP-Led restructurings are successful. Last year, Apax abandoned an announced restructuring of its 2007-vintage fund, stating that it was unable to garner sufficient investor support. A successful GP-Led restructuring needs cooperation from various parties, and it is important to understand and balance the various conflicting interests in order to achieve a successful outcome.

Navigating Conflicting Interests

A GP launching a fund restructuring should think carefully about the differing interests of all parties involved and manage these appropriately.

Conflicting interests

The GP is frequently on both sides of the transaction in asset deals (also called fund recapitalisations). The GP owes fiduciary duties to the investors in its existing fund which entails maximizing the value of the remaining assets; however, when selling those assets to a new vehicle it will manage, the GP will usually seek to reset the economics in the new vehicle which effectively means that its carried interest in the new vehicle will be tied to the pricing of the assets, potentially creating an incentive for the GP to agree to a lower price. The GP (or an affiliate) may also participate as a buyer, which would again incentivise it to lower the price.

"A successful GP-led restructuring needs cooperation from various parties, and it is important to understand and balance the various conflicting interests in order to achieve a successful outcome."

A secondary buyer may support a reset of the economics in order to re-incentivise the team, although in some cases this may not be necessary. In addition, the buyer will typically ask the GP to roll over its interest and make an additional commitment in the new vehicle in order to align its interests with those of the investors in the new vehicle. Depending on the circumstances, the buyer may also seek to limit the number or aggregate size of roll-over investors.

Certain investors will be motivated to sell, whether for liquidity reasons, portfolio management, to lock in gains (and/or limit further potential losses) or otherwise, and will therefore want to sell at an attractive price and limit their liability exposure. There is often sensitivity around the transaction costs and any financial advisor's fee, and negotiation should be expected as to whether the sellers in LP tender offers and non-rolling investors in asset deals should bear them.

Other investors, who may believe that with time more value may be achieved from the fund's assets, may seek to maintain the status quo, in other words, to keep the same terms in the new vehicle as in the existing fund, in particular as any accrued preferred return and potential GP clawback may be lost as a result of the restructuring.

Investors who want to stay in the existing fund may feel that a restructuring is premature, especially if the investments are performing well and the existing fund is not at the end of its term. For those who do not want to roll into the new vehicle, there is seldom a "do-nothing" option in asset deals allowing investors to retain their interests in the existing fund, and, whilst fund restructurings can be a great opportunity to build a relationship with new investors and provide a liquidity option to the existing ones, the GP may run the risk of disgruntling some of its existing LPs if it does not manage the process appropriately.

Continued on page 10

Private Equity Report
Spring 2018
Volume 18, Number 1

If managed properly, GP-Led restructurings can provide a win-win solution both for the GP and the different groups of investors with varying needs.

How to navigate conflicting interests

Transparency is key to navigating these conflicting interests. The GP should strive to communicate with its existing investors as early as possible and fully disclose the terms of the transaction. As to pricing, a third-party valuation and/or a fairness opinion may be obtained to give comfort to the existing investors but may not be sufficient to get their support. As investors gain experience in these transactions, they are increasingly likely to look at the terms of, and question the rationale behind, any proposed restructuring. In Europe, it is increasingly common for fairness opinions to be delivered by third-party advisors, which was previously seen primarily in the US. Depending on the scenario, careful thought should be given as to whether the economics should reset. GPs may be more likely to obtain investor support if the existing investors can maintain their *status quo* (the same terms in the new vehicle as in the existing fund). This can also be achieved by offering to the roll-over investors the option between two waterfalls in the new vehicle (which can be coupled with additional guarantees in relation to any potential GP clawback that may be lost as a result of the restructuring).

In LP tender offers, the buyer often sets a minimum and a cap on the percentage of interests to be acquired (often on a "first-come, first-served" basis to create momentum). Depending on the circumstances, buyers can also set a cap in asset deals if they wish to limit the number of roll-over investors and will typically seek to renegotiate certain existing fund terms in the new vehicle. For example, buyers may wish to insert new key person provisions to ensure continued management of the assets. In addition, if the GP effectively controls both the new vehicle and the selling fund, the buyer will want to carefully review the scope of the seller's representations and warranties, including with respect to the assets to be transferred to the new vehicle. Post-closing recourse of the buyer to the selling fund is also likely to be a key point in negotiation, given that the GP generally will want to distribute the purchase price to the non-rolling investors and liquidate the selling fund as soon as possible.

In LP tender offers, the purchase documentation is generally relatively balanced to encourage investors to sell and minimize negotiations, which can be challenging with multiple investors being direct parties to the purchase documentation. US tender offer rules may also impose timing constraints. Sellers in LP tender offers will be concerned with the scope of the excluded obligations (in other words, the obligations that are not assumed by the buyer) and the limitations on liability provisions to ensure that their exposure is limited (as in traditional secondaries), as well as their responsibility for any transaction costs and financial adviser's fees.

LP tender offers, which do not entail a renegotiation of the fund's terms, typically provide investors with an option to stay in the existing fund and maintain their *status quo* (although they may involve an extension of the fund's term with the buyer heavily influencing investors' decisions) and therefore can be an attractive alternative if there is a risk of insufficient investor support for an asset deal.

GP-Led Restructurings and Fund Documentation

In the US, the GP's role in secondaries and their potential conflicts of interest have been under scrutiny by the SEC, which has made several well-publicized comments to this effect. In Europe, these transactions do not seem yet to have caught the attention of the regulators. However, it is worth noting that under the AIFMD, fund managers must have a mechanism in place to avoid conflicts of interest and address them properly where they cannot be avoided.

Fund documents rarely contain any procedure explicitly allowing the GP to carry out a restructuring of the fund. In addition, depending on the structure of the transaction, the existing fund agreement sometimes

Continued on page 11

Private Equity Report
Spring 2018
Volume 18, Number 1

needs to be amended, requiring the consent of the investors. Asset deals, in particular, can create conflicts of interest (as the GP is frequently on both sides of the transaction), and the advisory committee should therefore be consulted as early as possible in the process. As fund restructurings become more common, advisory committee members are likely to have more experience on these transactions than the GP and may be increasingly likely to focus on the terms of, and rationale behind, the restructuring and not only on pricing. In some cases, a separate legal counsel may be engaged to represent the advisory committee. Advisory committee members may be reluctant to approve a fund restructuring, as it is not a typical role of the advisory committee, or may be conflicted and abstain from voting (and certain partnership agreements are unclear as to whether abstention counts as approval). To avoid these issues, in some cases the GP, following discussion with the advisory committee, has voluntarily chosen to seek a vote of all investors.

As these transactions become more common, should new funds coming to market include specific provisions in contemplation of future restructurings? In theory, a GP could in the fund agreement, seek to give itself enhanced rights to implement liquidity solutions in the future. In practice, however, this has not yet been commonly seen in relation to fund restructurings. It may prove challenging for a GP to find the right balance between spelling out what it might do and retaining enough flexibility (in particular since when a new fund is being raised, it is difficult to anticipate the timing or potential form of a restructuring that may become desirable down the road), and investors will be concerned about giving the GP too free a hand in the future. The standard provisions in current funds have not impeded the trend toward creative solutions, so there is perhaps little need for documentation changes. In any case, most players in the private fund market are now aware of the advantages a well-structured and balanced liquidity solution can afford all stakeholders, and thus the trend is likely to continue.

"As fund restructurings become more common, advisory committee members are likely to have more experience on these transactions than the GP and may be increasingly likely to focus on the terms of, and rationale behind, the restructuring and not only on pricing."

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Life Sciences Investing under Trump: Food and Drug Administration Developments

"This fast-moving regulatory landscape, combined with robust innovation in the life sciences sector, creates both opportunities and challenges for private equity sponsors."

While many other federal regulatory agencies have been marginalized or victims of regulatory paralysis, the Food and Drug Administration (FDA), under the leadership of Commissioner Scott Gottlieb, M.D., has implemented new initiatives intended to accelerate drug and device approvals and clearances, embrace innovation and new technologies, lower regulatory burdens and enhance therapeutic opportunities.

This fast-moving regulatory landscape, combined with robust innovation in the life sciences sector, creates both opportunities and challenges for private equity sponsors. As a result, the comprehensive regulatory diligence typically conducted on a potential acquisition target, or for managing exit timing or structure, needs to be accompanied by an understanding of the larger complex and multifaceted regulatory developments in the industry.

Initiatives Favorably Impacting Drug and Biologic Investment

Many of the FDA's new policies and initiatives help foster innovation and create an overall favorable environment for life sciences investing, both for companies working on innovative therapies and those producing generics and biosimilars.

- To help **accelerate the drug approval process**, the agency has established policies that support adaptive clinical trials. Adaptive trials, unlike traditional clinical trials, can be altered (in accordance with a preexisting protocol) in response to early results, allowing researchers to shift the study population or objectives, for example. A single adaptive trial could replace multiple lengthy and expensive trials and could lead to a shorter, less expensive approval process. In addition to adaptive trials, Gottlieb has also emphasized **the use of computation modeling** in a potential effort to abandon or modify the typical three stages of clinical trials.
- The FDA has placed a priority on **using real-world data and real-world evidence** to support its decision making. The FDA currently uses real-world data to monitor post-market safety and adverse events and to make

Continued on page 13

Private Equity Report
Spring 2018
Volume 18, Number 1

regulatory decisions. The 21st Century Cures Act requires the agency to go further and to develop a regulatory framework and guidance on how real-world evidence can be used to support approval of new indications for approved drugs or to support or satisfy post-approval study requirements.

"In what would be a significant deregulatory move, the FDA is planning to propose regulations this year that will increase access to prescription drugs by allowing them to be sold over-the-counter with added safeguards."

- Last year, the FDA issued its first three **approvals for gene therapy drugs**—part of a larger wave of immunotherapies that could one day lead to cancer vaccines and other breakthroughs. Currently there are hundreds of such gene- and cell-based treatments in clinical trials. To support the development of these therapies, the FDA has established a comprehensive policy framework as well as a **pathway for qualifying regenerative medicine therapies** to receive the FDA's fast track and breakthrough designations.
- The FDA announced its "Orphan Drug Modernization Plan" in June 2017 for treatments of rare diseases or conditions and, by the end of the year, had eliminated the entire backlog of pending orphan drug designation requests and **approved a record number of drugs with orphan indications**. In addition, the promise of targeted therapies, which may be extremely effective for certain subpopulations but not for others, has prompted the FDA to issue guidance on developing clinical trials for targeted therapies for small numbers of patients and on the diagnostic devices used alongside these therapies to identify patients eligible for treatment.
- In what would be a significant deregulatory move, the FDA is planning to propose regulations this year that will **increase access to prescription drugs by allowing them to be sold over the counter** with added safeguards. The FDA intends to promote innovative approaches to ensure that customers can self-select appropriate drugs on their own.

Initiatives Favorably Impacting Medical Device, Digital Health and Diagnostics Investment

As with drugs and biologics, the agency is actively working to promote innovation and first-in-class products in the realm of devices and diagnostics.

- To lessen the uncertainty in the device approval and clearance processes, the FDA issued final guidance **updating policy guidelines on the types of device modifications that require a new 510(k)** instead of mere documentation by the manufacturer. In addition, for the first time in well over a decade, the FDA **updated two "least burdensome" guidance documents** that implement the Congressional directive to eliminate unnecessary burdens that may delay the marketing of beneficial new products.
- The FDA announced plans to issue draft guidance that would **allow manufacturers to demonstrate substantial equivalence**, and obtain device clearance, using objective safety and performance criteria rather than having to compare a new device with specific predicate devices that may be decades old and difficult to obtain. Further, the FDA plans on issuing draft guidance in early 2018 that will place **increased focus on post-market**

Continued on page 14

Private Equity Report
Spring 2018
Volume 18, Number 1

follow-up studies to accelerate the market entry of medical devices and facilitate patient access to innovative products. The agency is also **reorganizing the Center for Devices and Radiological Health** by combining several of its review, compliance and surveillance functions into a single unit, the Office of Product Evaluation and Quality. The FDA expects this reorganization to increase the efficiency of the Center's activities, including application review.

"The agency is also reorganizing the Center for Devices and Radiological Health by combining several of its review, compliance and surveillance functions into a single unit, the Office of Product Evaluation and Quality."

- The FDA is in the process of **issuing new draft and final guidance documents related to medical software**, including guidance clarifying which categories of medical software functions and digital health technologies are subject to the FDA's jurisdiction and when to submit a 510(k) for a software change to an existing device. Areas that fall outside the FDA's jurisdiction—such as software meant for administrative support, patient decision support and electronic patient records, and to help maintain or encourage a healthy lifestyle—will face a lower regulatory burden and thus may be particularly attractive for new development. The FDA has also recently introduced the **Software Precertification (Pre-Cert) Pilot Program**, through which the FDA may pre-certify certain companies based on their quality systems and allow for a lower bar for any new digital health products distributed by these companies. We expect the FDA to continue to focus its regulatory efforts on high-risk products, while loosening the regulatory burdens on lower-risk digital health products, consistent with the mandates of the 21st Century Cures Act.
- Responding to what it calls a "new era of 3D printing of medical products," the FDA has issued guidance addressing technical considerations for manufacturers. The FDA also is in the process of **developing a regulatory framework for manufacturers of 3D-printed personalized devices**, but the guidance could result in higher regulatory burdens—including decreased flexibility and higher costs—for non-traditional manufacturers such as university hospitals that are already manufacturing 3D-printed devices for individual patients. As the FDA develops the regulatory framework, interested sponsors should pay close attention in order to take advantage of opportunities and avoid regulatory pitfalls.
- Companies offering certain types of **direct-to-consumer genetic tests** had several regulatory burdens reduced in November 2017. First, the FDA issued an order **exempting genetic carrier screening tests from premarket review**. This was followed by notice of the agency's intent to allow "genetic health risk assessment" (*i.e.*, predictive) tests to be exempted from premarket review under certain conditions. If finalized, manufacturers would only need a one-time review to ensure that they meet FDA requirements, after which they may market new tests without further review. In addition, in March 2018, the FDA approved for the first time a direct-to-consumer genetic test (using saliva) to test for three genetic mutations associated with breast cancer in people of Ashkenazi (Eastern European) Jewish descent.

Continued on page 15

- The debate continues around the regulation of **laboratory-developed tests** (LDTs)—in vitro diagnostic tests that are designed, manufactured and used within a single laboratory such as a hospital's in-house laboratory. The device industry is pitted against the clinical labs that develop and market diagnostics in the absence of FDA oversight (but subject to other Federal and state regulatory requirements). Commissioner Gottlieb is looking to Congress to establish the FDA's regulatory role in these products. In the meantime, the FDA is **encouraging LDTs to seek voluntary approval** and is pursuing ways to make the approval or 510(k) clearance process less burdensome. As one example, the FDA accredited the New York State Department of Health as an FDA third-party reviewer of in vitro diagnostics.

FDA Regulatory Initiatives with More Nuanced Implications for Life Sciences Investing

The implications of several FDA initiatives will depend on where the company sits in the market. Here we discuss four such areas: generic drugs, biosimilars, opioids and drug compounding.

- Regulations impacting generic drugs are of interest because the competition that generics introduce affects **drug pricing**. Commissioner Gottlieb has repeatedly expressed frustration with innovator companies that allegedly attempt to delay the entry of generic drugs into the market through two tactics: slowing down negotiations with generic drug companies over the use of the post-market risk management plans that innovators and generics are required to share for some drugs, and limiting generic company access to innovator drugs in order to perform the bioequivalence studies necessary for generic approval. In response, the FDA recently issued a guidance document **reducing the paperwork necessary for a shared Risk Evaluation and Mitigation Strategies (REMS) system**, and the agency is also expected to release guidance addressing generic drug company access to innovator drugs.
- The FDA **expanded the number of ways generic drug applicants can qualify for priority review** of their Abbreviated New Drug Application and issued multiple guidance documents intended to increase the efficiency of generic application review. The agency has also implemented strategies to **better publicize approved innovator drugs that are off-patent and off-exclusivity** and is working with the U.S. Pharmacopeial Convention (USP) to develop standards for those drugs.
- In 2017, the FDA **approved five biosimilars**, and Commissioner Gottlieb believes that biosimilar development, and resulting FDA approvals, is poised to significantly increase in the near future. He indicated that the agency will be releasing a **Biosimilar Innovation Plan** during 2018 that is intended to encourage biologics competition.
- The FDA is responding to the opioid crisis by increasing **heightened regulatory scrutiny of opioid products and their manufacturers**. It removed Endo Pharmaceuticals' Opana ER from the market and may take similar action against other products where it believes benefits no longer outweigh risks. The FDA is developing changes for immediate-release opioid labeling, requesting packaging changes to limit abuse, considering including the potential for abuse in the approval process for new opioid products and implementing more stringent post-approval obligations.
- At the same time, the agency is **encouraging innovations to treat opioid addiction** and the development of abuse-deterrent generic formulations of opioid products already on the market. The FDA has approved multiple therapies to treat opioid addiction, including a drug-device combination product (monthly

Continued on page 16

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buprenorphine injections) and a neurostimulator device developed by Innovative Health Solutions, Inc.

- The FDA has indicated that it aims to strengthen its **oversight over compounding pharmacies and outsourcing facilities** and intends to enforce higher quality standards. Since the 2012 meningitis outbreak that focused attention on the issue, the agency has conducted more than 425 inspections of compounding pharmacies and outsourcing facilities, during which it observed "problematic conditions during the vast majority of these inspections," and has overseen more than 140 recalls of compounded drugs. Notably, a **private equity fund was recently named in a Department of Justice lawsuit** targeting a compounding pharmacy for violations of the False Claims Act.

Private equity sponsors investing in the life sciences sector should be encouraged by the direction the FDA is currently taking. However, understanding the nuanced ramifications of the many new FDA initiatives is critical to making thoughtful and forward-looking investments in this industry. And it is equally important that private equity sponsors ensure that any FDA-regulated company has a sophisticated regulatory infrastructure in place to address compliance on an ongoing basis.

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