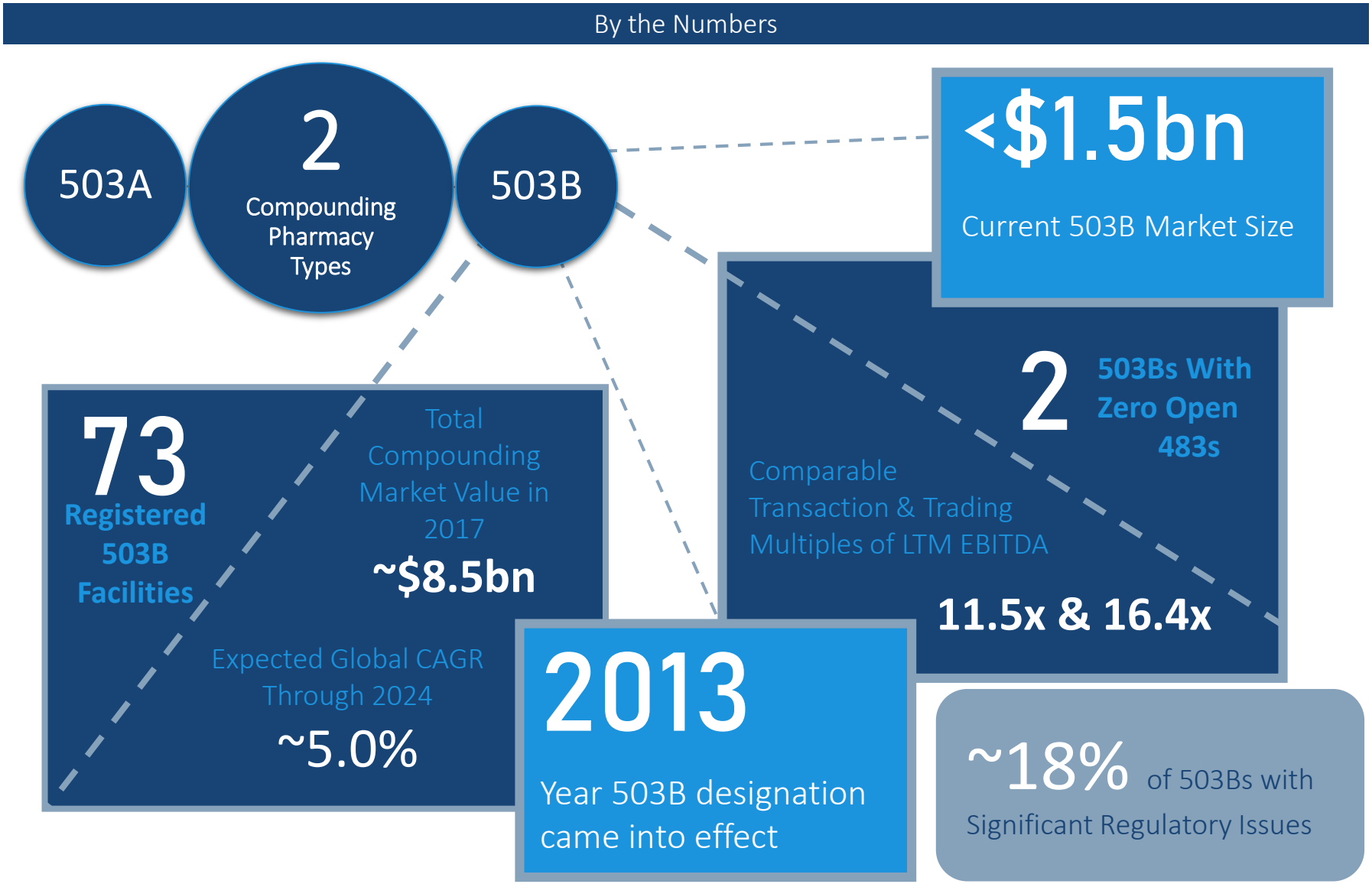
Compounding Pharmacy

Market Insight

December 2018

BOURNE PARTNERS

Compounding Pharmacies



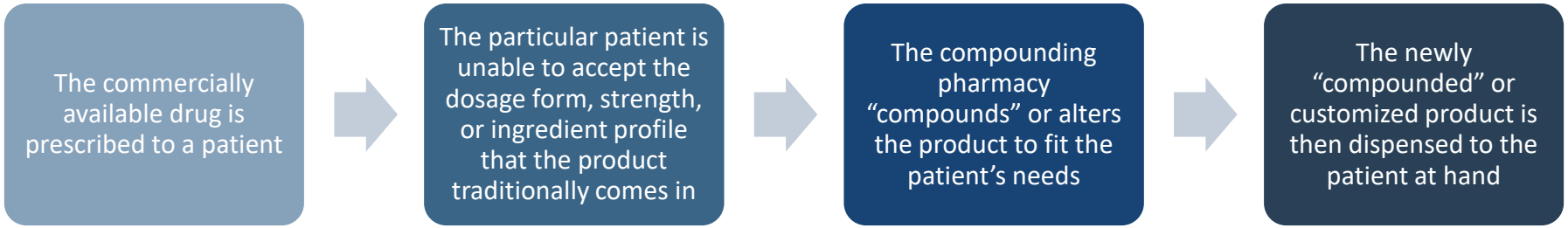
503A Compounding Pharmacies

What is a 503A?

- A 503A is a compounding pharmacy that makes or alters drugs that are prescribed by doctors for specific patients with needs that can't be met by commercially available drugs
  - For 503As, these drugs are made based on prescription demand, not in bulk like traditional drug manufacturing
- Traditionally, most 503As operate in hospitals and pharmacies when patients are unable to accept the commercial dosage form of a drug product or are allergic to one of the ingredients in a product
  - In these cases, compounding pharmacies make the proper dosage form or proper ingredient profile for the product so it is viable for the patient at hand, then dispense it at the adjacent pharmacy
- **503As are regulated *only* by the State Boards of Pharmacy** under USP<797> and some other guidelines - *soon to be USP<800> in December 2019*

503A Market Overview

- The 503A market is comprised of many small units that operate within the confines of a conventional pharmacy and **only compound products as needed on a "one-off" basis**
- 503As have traditionally focused on compounding various pain management topical cream products and altering the administration route of other drug products
- The compounding pharmacy market has been under the scrutiny of law enforcement for adding additional ingredients to these pain products and for Medicare fraud
  - Compounded pharmaceuticals may be subject to higher reimbursement under publicly funded healthcare programs like Medicare and therefore present an opportunity for fraud
- Although under legal scrutiny, 503As are not regulated as stringently from a manufacturing perspective as 503Bs
  - The inherent risk of compounding a product for a single prescription is much smaller than for compounding large batches of products for medical office use



Sources: Global Market Insights, The FDA Group, CapitalIQ

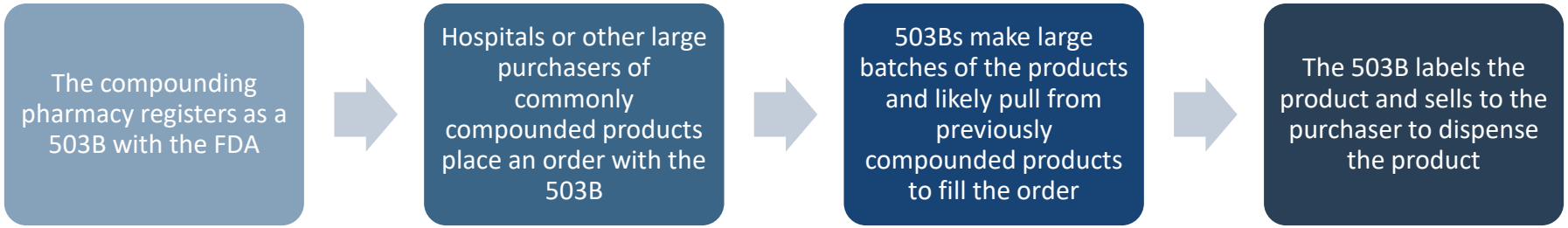
503B Outsourcing Facilities

What is a 503B?

- 503Bs are "outsourcing facilities" that manufacture large batches with or without specific prescription demand to be sold to healthcare facilities for medical office use in hopes of bridging the gap between traditional pharmacy compounding and industrial manufacturing
- The major differences between 503As and 503Bs lie in their business model and the regulatory oversight:
  - **In the 503B business model, the compounder can produce products in bulk to be used as prescription demand comes in as opposed to one-off compounds** or performing simpler procedures like "ad-mixing"
  - **503Bs require full cGMP compliance like contract manufacturing organizations ("CMO")**
    - Specifically, 503Bs must submit multiple batches of each drug for testing and stability studies due to shelf-life/beyond-use date ("BUD") concerns
- Another way that 503Bs enter the market is by manufacturing drugs that are currently experiencing a shortage

503B Market Overview

- In 2012, New England Compounding Center ("NECC") had a breakdown in sterile practices with some of its sterile injectable products that caused a meningitis outbreak, sickening over 600 people
- In response to this incident, the FDA passed the Drug Quality and Security Act ("DQSA"), adding section 503B to the Food, Drug, & Cosmetic Act ("FDCA"), which delineated the traditional compounder (503A) from the large batch compounder (503B) through heightened regulation of 503Bs
- Following the formal definition of 503Bs in 2013, there was significant lobbying, aimed at keeping the power of 503Bs in check by imposing the same FDA regulations that apply to industrial drug manufacturers to these 503Bs, many of whom resemble those large traditional drug manufacturers
- Today, despite the increased regulation and **oversight by both the State Boards of Pharmacy and the FDA**, outsourcing has become more popular due to its many benefits



Sources: Global Market Insights, The FDA Group, CapitalIQ, Proprietary Research

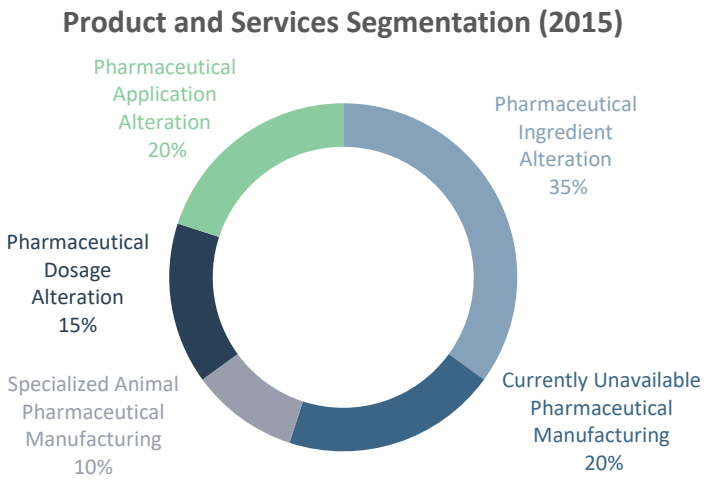
Market Landscape

Growth Dynamics

- Pharmaceutical compounding began in the 1930s when ~60% of medications were compounded – this would slow down in the 1950s with the advent of large scale drug manufacturing and then regain prevalence in the 1990s when physicians began to fully realize the benefits of custom medications
- **In 2017, the Compounding Pharmacies Market as a whole was valued at ~$8.5bn and is expected to grow to ~$12.5bn by 2024, an implied CAGR of ~5.0%**
  - **The 503B market currently sits at < $1.5bn**
- There are various drivers of the growth in compounding:
  - The largest driver is the increasing life expectancy/increasing elderly population, as this population is more likely to be intolerant of the commercially available dosage form of pharmaceutical products and requires suitable alternatives
  - Other drivers include the rising prevalence of cardiovascular disease, diabetes, hypertension, and respiratory disorders
  - The convenience benefits, such as reduction in the number of doses through combining multi-dose prescriptions into single-dose and formulating medications into specific strengths or administration vehicles, are also propelling growth
- Increased regulatory oversight in the compounding space has made it more expensive for hospitals to produce compounded products internally, boosting the demand for large scale 503Bs
- **Following the passage of DQSA, the number of facilities registering as 503Bs jumped; but growth has slowed since**
  - **There are now 73 FDA registered 503B facilities in the US, a minimal increase from 71 in 2014**

Competitive Landscape

- The compounding pharmacy space is very fragmented because 503As typically operate in-house for a hospital or a retail pharmacy, and many 503Bs are owned by a larger organization that also participates in another functional piece of the pharmaceutical supply chain
- As mentioned previously, the prevalence of 503B facilities is increasing in the industry, yet **the 503B market is still currently underpenetrated**
- The oral product segment has dominated the market of late as high demand for ease of administration dosage forms such as oral liquid compounds, capsules, and granules has fueled growth
  - Other segments holding large market share are the adult treatment and hormone replacement segments



Sources: Reuters, Global Market Insights, FDA

Market Trends

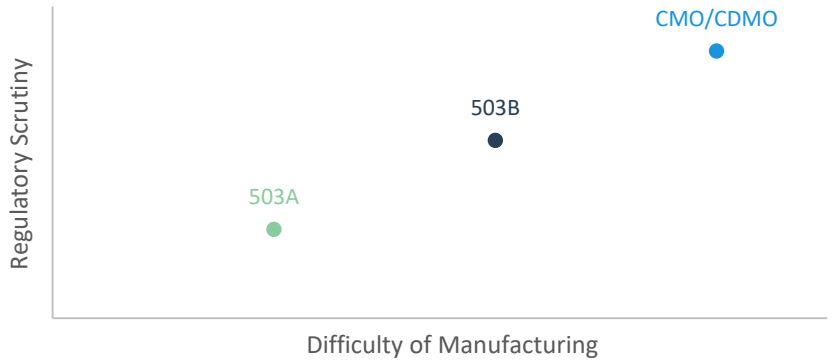
Outsourcing

- Due to the increased regulatory scrutiny on compounders as a whole, 503Bs offer multiple value-adds such as quality assurance and cost reduction; in response, hospitals are outsourcing compounding more aggressively
- **Today's 503Bs offer cheaper and more viable alternatives to the traditional 503A model, allowing 503Bs to become a more integral part of the hospital drug supply chain**
- Companies already investing in cGMP facilities are specifically positioned to take advantage of this trend as noncompliance becomes more and more costly
- The table below demonstrates some of the added benefits and oversight found with the 503B model

503B – Outsourcing Solution	
	Requires cGMP compliance and FDA oversight on top of USP<797>
	Able to compound large batches of product for medical office use
	Regular stability studies
	Longer use-dating (BUD)
	Fully staffed Quality Assurance departments
	Custom labeling abilities

Regulatory

- The heightened oversight of compounding pharmacies has restricted the growth of 503Bs
  - Following the delineation in 2013, the number of companies registering 503B facilities spiked; over the last few years, this number has stalled as more focus is placed on regulatory compliance
- The Drug Quality and Security Act provides a mechanism for FDA oversight and regulation, resulting in increased scrutiny
  - **Increased oversight has resulted in a shockingly high number, ~18%, of 503Bs receiving Warning or Untitled Letters, Consent Decrees, or ceasing operations to some extent**
  - **Only 2 previously inspected 503Bs do NOT have an outstanding Form 483**
- The overall dynamic for registered 503Bs is auspicious going forward as this regulatory pressure creates a barrier to entry
  - **503Bs that are able to get a firm handle on the Quality and Regulatory piece will reap hefty rewards due to the market's increased demand for the 503B model**



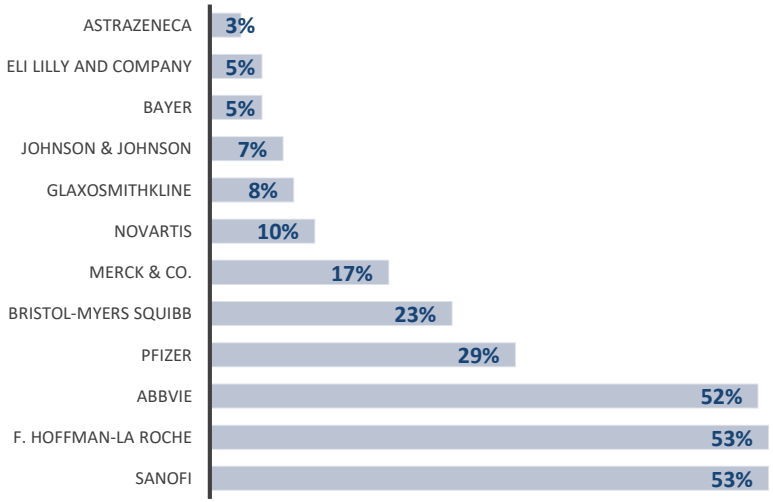
Sources: Proprietary Research, Healthcare Investor, FDA

Market Trends (cont.)

Biologics

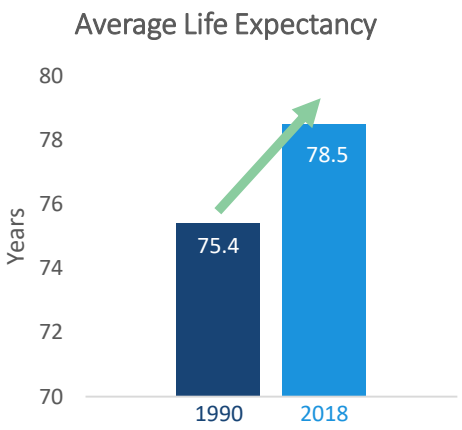
- The transition to biologics and genetically-modified medications may present opportunities for compounders
- Modifiable medications are often compounded at manufacturing plants and sent to pharmacies
- **503Bs are uniquely suited to produce and distribute biologics due to the cGMP compliance requirement**
  - **These capabilities allow them to streamline the supply chain and drive down production costs for these products**
- As the prevalence of biologics continues to increase, compounding pharmacies are in an ever-better position to benefit from the trend

Change in % Revenue from Biopharma, 2000-12



Other General Trends

- Despite increased regulatory scrutiny and oversight, the aging population has supported continued growth in the compounding pharmacy market, particularly with the help of Medicare Part D
- Amazon's move into the pharmaceutical distribution market with its acquisition of PillPack will shake up the pharmacy and distribution industries by disrupting the normal "brick-and-mortar" retail pharmacy operations, which could bleed into the compounding pharmacy market, specifically for 503As
- As technological capabilities continue to grow, the ability to innovate manufacturing/compounding techniques is altering older industry practices, specifically for larger players



2018

amazon

PillPack

Implied EV: ~$1.0bn
EV/LTM Rev: ~9.5-10.0x

Sources: Mckinsey, Healthcare Investor, CNBC, NCHS

Regulatory Case Study - PharMEDium

Developments

- PharMEDium (the "Company") is a subsidiary of AmerisourceBergen Corporation ("ABC") that operates compounding pharmacies, specifically 503B outsourcing facilities
- Following its receipt of a series of Form 483 reports from an FDA inspection, PharMEDium has voluntarily suspended production activities at its Memphis, TN facility
  - Some of the more common issues included failing to have procedures that adequately protect against contamination or ensure quality control in the facilities

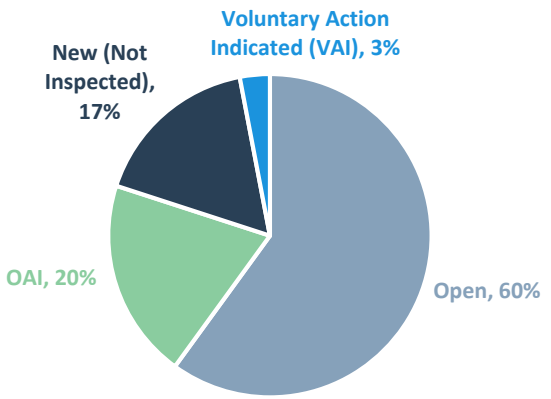
Current Situation

- In Q1 2018, the Company began taking corrective actions across its facilities to correct the observations from the FDA
- When asked, ABC stated that the Company has tapped cGMP compliance experts to audit PharMEDium's largest compounding facility in Memphis, TN and has implemented third party compliance monitors at all sites
  - Throughout the implementation of these actions, PharMEDium has been in contact with the FDA and DOJ, stating that it will not restart commercial operations at the Memphis facility pending further feedback

Implications

- As one of the largest compounders in the US and a subsidiary of a healthcare services industry giant, **PharMEDium's struggles with the stringent regulatory oversight highlight the complications that 503Bs are encountering across the board**
- Following the 503B designation and the increased oversight that accompanies it, many companies are experiencing similar issues
  - **As of October 2018, almost all 503Bs were in some form of Official Action Indicated ("OAI") or "pending" status; there are currently 7 outstanding Warning Letters and 1 Consent Decree of Permanent Injunction (Delta Pharma, June 2018)**
- This case emphasizes the notion that 503Bs who are able to handle the added regulatory scrutiny will be uniquely suited to take on this growing market

Regulatory Status of Registered 503B Outsourcing Facilities



Sources: BioPharma Dive; Market Exclusive; Proprietary Research, FDA

Market Outlook

Investment Trends

- Over the last 12 months there has been relatively little M&A activity in the space as **most players are focused on getting a firmer grasp of the Quality and Regulatory aspect for their current operations**
  - The number of 503Bs is roughly the same today as in 2013, following the passage of DQSA (73 today vs. 71 in 2014)
- However, **there has been significant capital deployed in the space since the 503B delineation**
  - Some traditional manufacturers such as Nephron Pharmaceuticals and Exela Pharma Sciences, who were previously sterile generic manufacturers, invested in compounding capabilities to add to their existing drug development and CMO businesses
  - **Other investment has come from private equity interest** with Enhanced Healthcare Partners (SCA Pharmaceuticals), Bain Capital (QuVa Pharma), SV Health Investors (Leiters), and many more investing in the 503B space
    - This was most recently exhibited by Advantage Capital's $3.6mm investment in RXQ Compounding to expand facility capacity and increase R&D
- Fagron, one of the largest compounders in the space, acquired All Chemistry Do Brasil LTDA, a supplier of raw materials to compounding pharmacies, in October 2017
  - This type of acquisition shows a move towards supply chain integration and an added focus on its 503B business
- Many other investments by 503Bs are internal investments focused on expansion and Quality and Regulatory improvements
  - These investments can come in many forms with one practical example being PharMEDium/ABC as previously mentioned

Going Forward

- Due to rising demand for compounded drug products, compounding pharmacies will continue to grow in prevalence
- **Despite more intense regulatory scrutiny, the 503B model is the more cost efficient, scalable, and profitable approach to meeting this demand**
- Moving forward, we expect this movement to drive M&A from multiple angles:
  - We expect to see **existing 503Bs acquiring other 503Bs or cGMP facilities** to expand reach, capabilities, or both
  - **Non-503B players such as CMOs/CDMOs or financial buyers will likely begin acquiring 503Bs** to move into the space and/or expand service offerings
  - Due to the regulatory issues, **some 503Bs will be forced to sell**, which could be an opportunity for consolidation from a handful of leaders in the space that are looking to expand capacity and reach, or for value investors that are open to turnaround situations
- Alongside the growth in M&A activity, **we expect continued focus on/investment in Quality and Regulatory compliance** for many of these companies/facilities as only 2 of the 73 currently FDA registered 503Bs do NOT have an outstanding 483 report
  - **cGMP compliance is expensive, but noncompliance is even more costly**

Market Sentiment

M&A Activity

Announced Date	Target	Buyer	Geographic Location	Enterprise Value	LTM Revenue	LTM EBITDA	EV / LTM Revenue	EV / LTM EBITDA
Nov-17	Leehar Distributors, Inc.	Diplomat Pharmacy, Inc.	USA	$595.6	$388.0	$41.0	1.5x	14.5x
Nov-17	Salus Pharmacare Inc.	Centric Health Corporation	Canada	3.2	NA	0.5	NA	6.8x
Aug-17	Quantum Pharma Plc	True Nature Holding, Inc.	United Kingdom	199.9	119.5	8.2	1.7x	24.4x
Apr-16	Diplomat Specialty Pharmacy of Los Angeles County, Inc.	Diplomat Pharmacy, Inc.	USA	75.7	400.0	9.0	NM	8.4x
Apr-16	Integrity Compounding Pharmacy, LLC	True Nature Holding, Inc.	USA	1.0	0.9	NA	1.1x	NA
Oct-15	PharMEDium Healthcare Holdings, Inc.	AmerisourceBergen Drug Corporation	USA	3,060.8	405.7	96.0	7.5x	31.9x
May-15	AnazaoHealth Corporation	Fagron NV	USA	97.8	NA	16.3	NA	6.0x
Jun-13	CarePoint Partners, LLC	BioScrip, Inc.	USA	221.1	140.5	NA	1.6x	NA
			Median	$148.9	$264.3	$12.7	1.6x	11.5x
			Mean	$531.9	$242.4	$28.5	2.7x	15.3x
			Min	$1.0	$0.9	$0.5	1.1x	6.0x
			Max	$3,060.8	$405.7	$96.0	7.5x	31.9x

- Because the 503B delineation is relatively new and the market is still nascent, there are few pure M&A comps
  - In order to look at M&A valuations in the space, we looked at compounding pharmacy transactions alongside specialty pharmacy transactions – an adjacent subsegment of the Pharma Services market
- This set of precedent transactions exhibits a **median EV multiple of 11.5x LTM EBITDA**
- Moving forward, **we expect M&A Activity, both volume of deals and multiples, to pick up as the market matures** and demand for the 503B model continues to grow

Source: CapitalIQ; all estimates as of Nov. 19, 2018
NM – Not meaningful; NA – Not Available

Market Sentiment (cont.)

Trading Valuations

Company	Ticker	Share Price	LTM Sales	LTM EBITDA	LTM EPS
Diplomat Pharmacy, Inc.	NYSE:DPLO	$15.08	$5,287.0	$106.6	$0.14
Imprimis Pharmaceuticals, Inc.	NasdaqCM:IMMY	$4.77	$37.3	($3.4)	($0.54)
BioScrip, Inc.	NasdaqGS:BIOS	$3.65	$707.9	$46.8	($0.21)
Fagron NV	ENXTBR:FAGR	$17.07	$522.5	$98.9	$0.59

Company	Ticker	Enterprise Value	EV / Sales	EV / EBITDA	P / E
Diplomat Pharmacy, Inc.	NYSE:DPLO	$1,744.4	0.3x	16.4x	NM
Imprimis Pharmaceuticals, Inc.	NasdaqCM:IMMY	$120.1	3.2x	NM	NM
BioScrip, Inc.	NasdaqGS:BIOS	$947.3	1.3x	20.2x	NM
Fagron NV	ENXTBR:FAGR	$1,530.0	2.9x	15.5x	28.8x
Median		$1,238.6	2.1x	16.4x	NM
Mean		$1,085.4	2.0x	17.4x	NM
Min		$120.1	0.3x	15.5x	NM
Max		$1,744.4	3.2x	20.2x	NM

- Once again, the youth of the 503B delineation limits the number of publicly traded pure-play compounding pharmacies
- In order to look at public market valuations in the space, we looked at companies that specifically focus on or have divisions devoted to compounding, such as Fagron and Imprimis, alongside specialty pharmacies like Diplomat and BioScrip
- The market is valuing these companies at a **median EV multiple of 16.4x LTM EBITDA**, a rich figure that we would expect given the valuations in the broader Pharma Services market
- As the Compounding Pharmacy market matures and companies achieve scale, **we expect to see more companies looking to the public markets as a viable source of capital**

Source: CapitalIQ; all estimates as of Nov. 26, 2018
NM – Not meaningful; NA – Not Available

Possible Buyers / Investors

"Pure-plays"

- Pure-play compounding pharmacies solely perform pharmaceutical compounding functions such as the 503B facilities
- A few examples of the larger players in this space that are solely compounders or have divisions devoted to compounding are QuVa Pharma, PharMEDium, and Fagron NV
- These companies could be looking to expand capacity or specific capabilities

Specialty Pharmacy

- Many larger pharmacy and specialty pharmacy companies have divisions that compete in the compounding space or could be looking to expand into this market
- Some of these companies include Coram Rx (now owned by CVS Caremark), Diplomat Pharmacy, and Avella Pharmacy
- There are also smaller specialty pharmacy players, such as MediMix, that could be interested in expanding into this area

Financial

- SV Health Investors, Frazier Healthcare Partners, HIG Capital, and Advantage Capital Partners are all private equity firms that have previously invested directly in compounding pharmacies
- Other private equity firms such as Bain Capital and Enhanced Healthcare Partners have portfolio companies in the space

Other Possible Investors

- Outside the traditional three buckets profiled on this slide, there are some non-traditional players in the pharmaceutical industry that could be interested in investing in or moving into the compounding market
- Contract manufacturers could also be interested in taking a look as a play to expand capabilities/offerings in the drug manufacturing space
- Other possible candidates would be large hospital/healthcare systems that supply large amounts of compounded products to patients or other players within the traditional pharma distribution channel

Sources: CapitalIQ, Pitchbook

Key Takeaways

- The 503B market is ripe for continued growth as the market matures and demand for compounding grows
- The biggest obstacle facing the industry today is the Quality and Regulatory scrutiny causing issues for nearly every 503B
- Operators who can successfully navigate the FDA's oversight will be poised to capture market share
- Bourne Partners anticipates M&A activity to increase as the 503B market matures, driven by:
  - Platform and bolt-on acquisitions by private equity looking to play in the high growth and fragmented 503B market
  - Consolidation by a handful of larger 503Bs looking to expand market share and capabilities
  - Entry into the 503B market via M&A by other pharma service providers including traditional manufacturers, specialty pharmacies, and other players within the pharmaceutical supply chain
  - Forced exits or asset sales due to regulatory and/or financial distress from operators who cannot get a handle on Quality and Regulatory
- As a nascent industry, there is not yet a robust set of 503B specific trading and transaction comparables to pull from. However, Bourne Partner's M&A advisory business has already seen strong interest in and demand for quality 503B assets
  - As a sub-segment of the broader Pharma Services industry, Bourne Partners believes quality 503B businesses will trade and transact at similar multiples to other Pharma services companies; currently in the mid to high teens as a multiple of LTM EBITDA
  - Bourne Partners expects strong demand for quality 503B assets for the foreseeable future

Bourne Partners Senior Team

Bourne Partners is Comprised of Experienced Advisory and Investment Professionals, Healthcare Executives, and Operating Partners

Banks Bourne
Chief Executive Officer

Minor Hinson
Chief Investment Officer

Jeremy Johnson
Managing Director

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Lindsey Stevens
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- Over 50 years of combined pharmaceutical, pharma services, and consumer health/OTC experience
- Over 100 years of combined investment banking and private equity transaction experience
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- Licensing Agreements
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Office Information

550 South Caldwell Street, Suite 900
Charlotte, North Carolina 28202
www.bourne-partners.com
Tel: 704-552-8407
Fax: 704-714-8363

Contact Details

Jeremy Johnson
Managing Director
Office: 704-714-8351
Mobile: 704-201-2323
jjohnson@bourne-partners.com

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