

## Eagle Pharmaceuticals Inc. (EGRX)

Overweight

A Unique Approach to the Hospital Injectibles Arena; Initiating at Overweight

### CONCLUSION

We are initiating coverage of Eagle Pharmaceuticals with an Overweight rating and \$22 PT. Eagle is building a unique business model in the hospital injectibles space, using a 505(b)(2) filing strategy to bring generics to market with improved attributes over innovator products. This also enables EGRX to more easily maneuver around innovator intellectual property, possibly driving first-to-market positioning, as well as bring brand injectibles to market, in our view. With a 505(b)(2) filing on a generic of chemo agent bendamustine (Teva's \$700M+ brand Treanda) pending plus the advancement of an enhanced form of dantrolene (more on this below) and additional 505(b)(2)-based generic filings on the way, we believe EGRX is well-positioned for cash generation in the 2016/2017 timeframe. Given the numerous shots-on-goal, EGRX shares are trading at a compelling risk/reward with a current market cap of around \$200M.

- **Filing on bendamustine leads a growing list of "enhanced" injectible generic shots-on-goal.** FDA action on EGRX's liquid, ready-to-dilute form of bendamustine is expected by 7/6/14. Another filing on a form of the product requiring a shorter infusion time versus the brand is expected by early 2015. Though Teva has initiated litigation versus EGRX, it is only defending a single polymorph patent that our consultants believe is narrow and that EGRX, with its liquid form, is less likely to infringe upon (on a simplistic level, a polymorph denotes a solid structure). All other filings are traditional abbreviated NDAs on Teva's lyophilized powder form (i.e., potentially harder for these filers to show non-infringement). As such, we could very well see EGRX enter the market as the only generic following the expiry of Treanda's orphan status in April 2016. That said, even if EGRX were to eventually compete alongside a number of vanilla generics, trough sales for EGRX would still be attractive in our view. For instance, EGRX could easily have annual sales of \$40M-\$55M in a five-player market (likely a \$900M+ market by 2016 in brand dollars, cut by 75% in value due to competition, with EGRX capturing roughly 20%-25% of volumes).
- **A new form of dantrolene offers two shots-on-goal, one of which could be transformative.** EGRX's form of dantrolene for malignant hyperthermia (MH) requires only a single vial versus 12 for the current version (EGRX submitted its filing in 1/14), which was approved for MH in 1979. This is a near \$20M market that we believe should readily migrate over to EGRX's product. With MH being a dire (though rare) emergency (i.e., hospitals have to stock the product), we could envision pricing power over time. Given that there appears to be a relationship between MH and exertional heat stroke (EHS), EGRX is pursuing development of dantrolene in this setting. A single vial can easily be stocked by first responders, not unlike how near \$1B product Epi-Pen is stocked. We believe dantrolene in EHS could be commercialized in the 2017/2018 timeframe, with at least \$200M in sales potential in EHS.

### RISKS TO ACHIEVEMENT OF PRICE TARGET

Pipeline setbacks and risks related to patent litigation.

### COMPANY DESCRIPTION

Eagle is focused on optimized generic injectibles.

YEAR	REVENUE (US\$ m)						EARNINGS PER SHARE (US\$)					
	Mar	Jun	Sep	Dec	FY	FY RM	Mar	Jun	Sep	Dec	FY	FY P/E
2014E	2.0E	1.8E	1.5E	1.3E	6.5E	31.9x	(0.36)E	(0.34)E	(0.38)E	(0.44)E	(1.53)E	NM
2015E	2.0E	2.0E	2.3E	2.6E	9.0E	23.0x	(0.43)E	(0.46)E	(0.47)E	(0.47)E	(1.84)E	NM
2016E	—	—	—	—	143.9E	1.4x	—	—	—	—	2.49E	6.0x

PRICE: US\$14.92

TARGET: US\$22.00

17x 2018E non-GAAP EPS of \$2.20, disc.  
20%

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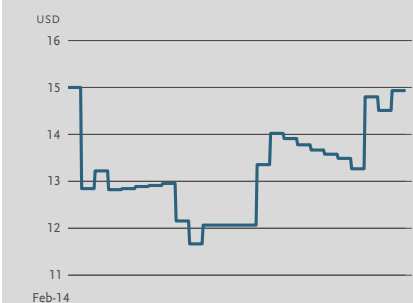
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Changes	Previous	Current
Rating		Overweight
Price Tgt		US\$22.00
FY15E Rev (mil)	—	US\$9.0
FY16E Rev (mil)	—	US\$143.9
FY15E EPS	—	US\$(1.84)
FY16E EPS	—	US\$2.49
52-Week High / Low	US\$16.44 / US\$11.41	
Shares Out (mil)	13.9	
Market Cap. (mil)	US\$207.4	
Book Value/Share	US\$3.25	
Net Cash Per Share	US\$3.95	
Debt to Total Capital	0%	
Yield	0.00%	
Fiscal Year End	Dec	

### Price Performance - 1 Year



Source: Bloomberg

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## INVESTMENT HIGHLIGHTS

We are initiating coverage of Eagle Pharmaceuticals with an **Overweight** rating and **\$22** price target. We believe that EGRX's focus on improving upon the limitations of hospital-based injectible products positions the company for significant value creation. The business model is centered around NDA filings via the 505(b)(2) pathway, which in the context of generics essentially enables EGRX to more readily maneuver around innovator intellectual property, potentially enabling first-to-market positioning, but also enabling potentially durable volume share (in the context of competition with traditional generics) given EGRX's formulation enhancements over innovator products. The 505(b)(2) model also enables EGRX to leverage its formulation expertise to bring traditional brand products to market as well. In short, EGRX is building a balanced business focused on injectible generics and brands, supported over time by a concentrated sales infrastructure in the hospital setting (as is the case with a number of other emerging peers such as Sagent (SGNT) and Akorn (AKRX)). The pipeline is robust, in our view, led by a generic form of the chemotherapy agent bendamustine (trade name is Treanda; a near \$700+ million brand) that nonetheless offers enhancements over the brand in terms of ease of administration. EGRX is also advancing an enhanced form of dantrolene for the niche setting of malignant hyperthermia (MH) and for exertional heat stroke (EHS), a potentially transformative opportunity. At a minimum, we believe that sustainable, trough annual revenues, reflecting contribution from generic bendamustine and dantrolene in MH alone could be around \$60-\$80 million. That said, we could (and should) easily see contribution from other 505(b)(2) opportunities over time (more on this below). Given that backdrop, not to mention the potentially transformative opportunity for dantrolene in EHS, EGRX shares are trading at a compelling risk/reward in the context of a market cap of around \$200 million. Our price target of \$22 is based on our 2018 EPS estimate of \$2.20, times a P/E of 17x, discounted at 20% (and is supported by our 10-year discounted cash flow (DCF) analysis).

**Several generic injectible shots-on-goal with bendamustine (Treanda) at the top of the list.** EGRX's work on bendamustine is illustrative of the company's focus on making generics that contain enhancements over the innovator product. EGRX's product that has been filed with the FDA via 505(b)(2), with an action date of 7/6/14, is a liquid formulation that does not require reconstitution (as opposed to the brand, which is a lyophilized powder that needs to be reconstituted). EGRX is also planning a second filing in early 2015 on the same formulation, though in this case requiring a shorter infusion time (around 10 minutes versus the current 30-60 minute infusion time for the brand). We know of at least 9 traditional abbreviated NDA (aNDA) filers on Treanda, with 30-month stay expiries as early as 2Q16. Based on feedback we have received from our patent consultants, we believe that EGRX's formulation has a reasonably good chance of demonstrating non-infringement versus the only Treanda patent (#8,445,524, which expires in March 2029) that Teva is defending in this particular case (bearing in mind that bendamustine is an old compound with a thin patent estate). On a simplistic level, the '524 patent has claims surrounding a polymorphous form of bendamustine (i.e. a solid, specifically crystalline structure). Given that EGRX's product is a liquid form, it would stand to reason that it is unlikely that it would run afoul of the '524 patent. Thinking about the opportunity a bit differently, even if the traditional aNDA filers were also to show non-infringement, translating into a relatively crowded market, the opportunity for EGRX would still be robust. If we assume that there are multiple generics starting sometime in 2016 (i.e., after patent trials and 30-month stays; let's assume a five-way market including the brand), a 75% discount to the brand price (i.e., around a \$900 million brand market by then, shrinking to \$225 million annually), and relatively equal volume share among the various entrants, EGRX's annual sales on its product would still be around \$40-\$55 million (and one could argue that its share and

trough sales could be higher given EGRX's enhancements over the brand and generic equivalents).

**Enhanced dantrolene formulation also a key driver; malignant hyperthermia (MH) opportunity could prove to be an attractive stream of revenue over time.** Dantrolene is a ryanodine receptor antagonist that was originally approved in 1979 for MH, a rare, life-threatening condition triggered by exposure to certain anesthesia agents. MH is characterized by a hyper-metabolic state in skeletal muscles leading to uncontrolled high body temperature, rapid heart rate and muscle breakdown. Susceptibility to MH is inherited, and typically the result of mutations involving the ryanodine receptor. The current form of dantrolene (the only maker of the brand is JHP Pharma) requires 12 vials (a 240 mg dose in 720 mL of fluid), whereas EGRX's form of the product (an NDA was submitted in January 2014) enables the same dose to be administered in only 5 mL of fluid (a single vial, with far more rapid reconstitution). In short, it would be intuitive for hospitals to rapidly switch to stocking EGRX's enhanced form of dantrolene. Though this is only a \$20 million annual market (the wholesale average cost (WAC) of a 240 mg dose is around \$1,050), we could envision pricing power over time for EGRX, bearing in mind that MH is typically fatal when untreated, meaning that hospitals must carry inventory of the product. Given that we often see pricing power for niche-like legacy brands (both in the institutional and retail pharmacy settings; Akorn's 50% price increase on the sedative pentobarbital (Nembutal) after it acquired rights to the brand from Lundbeck in December 2011 is a useful example), we would not be surprised to see those same dynamics come into play longer-term for EGRX's form of dantrolene. In other words, what is now a \$20 million market could in our view easily inch closer to \$25-\$30 million or more over time.

**Dantrolene in exertional heat stroke (EHS) a potentially transformative opportunity.** In our conversations with key opinion leaders and in our review of the available literature, there is evidence that the same genetic predispositions that can result in MH can also lead to EHS. Theoretically, a form of dantrolene that can be administered in a single vial can be a potential tool used by first responders and hospitals to treat EHS patients. This is bearing in mind that beyond cooling the patient via ice packing and/or cold IV fluids, there are no pharmacologic treatments available for EHS. Animal model work done by EGRX (specifically a pig heat model) pointed to significant lowering of core body temperature in cases where dantrolene plus traditional cooling treatments were used versus cooling treatments alone. EGRX is working with the FDA on the design of a pivotal study (most likely in a military setting, where heat stroke is certainly not unheard of), which could begin as early as 2H14. Key opinion leaders we spoke with noted that primary efficacy measures assessing organ function/failure and core body temperature should be sufficient for a label expansion (as opposed to a mortality measure, which would require a much larger study), bearing in mind that dantrolene is a well-known quantity with a relatively clean safety track record. The most appropriate treatment paradigm to which one can compare dantrolene in EHS is EpiPen, a near \$1 billion product that is stocked by hospitals, schools, first-aid stations, and first responders (as well as individuals) for emergency treatment of anaphylaxis.

**Additional 505(b)(2) filings most certainly on the horizon; Eagle laying the foundations of a fully integrated hospital injectibles platform.** Eagle is planning a 505(b)(2) filing in 1H15 on a ready-to-dose form of the anti-coagulant bivalirudin (The Medicines Company's Angiomax, which had 2013 brand sales of around \$550 million). The brand, which is supplied as a 250mg vial of lyophilized powder, requires both reconstitution and dilution. There are two patents with expiries in January 2029 (beyond the composition patent, which expires in June 2015) that have various claims, broadly speaking, surrounding manufacturing processes and preparation. Patent consultants we have spoken with noted

that with a 505(b)(2) filing (i.e., EGRX is not claiming “sameness”, but rather a different formulation), EGRX has more room to maneuver around what our consultants believe are relatively narrow claims. Interestingly, MDCO settled its litigation with two paragraph IV filers (Teva and APP) allowing for launches in May 2019 and June 2019, respectively (the launch dates in the context of patent expiries in 2029 suggest that MDCO is eager to have some measure of certainty on the future of this franchise). Beyond Teva and APP, we know of four other paragraph IV filers, though EGRX is the only 505(b)(2) filing. Though it is not clear if EGRX will be able to have a first-to-market advantage, this is a case where even in a market with multiple generics, EGRX, in our view, could sustain reasonably strong volume share given the enhancements in its formulation. We note that EGRX is also planning a 505(b)(2) filing on its version of lung cancer treatment pemetrexed (Eli Lilly’s Alimta, a near \$1.2 billion brand in the U.S.) and will likely disclose additional 505(b)(2) generic opportunities that are moving towards NDA filings in the next 12-18 months. We note that these additional opportunities are not reflected in our estimates for the next 5-6 years.

## | VALUATION

We base our \$22.00 price target on our 2018 EPS estimate of \$2.20, times a P/E of 17x, discounted at 20% for 3.0 years. We use 2018 since it is a better reflection of steady-state profitability (contribution from dantrolene and bendamustine, though no contribution from other generic products). Our model includes contribution from Eagle's bendamustine and dantrolene products, launching in early 2016 and early 2015, respectively. Our model reflects continued R&D expenditures to support the rest of the product pipeline, but does not reflect revenue contribution from these pipeline products. In that kind of scenario, we expect Eagle to reach meaningful profitability in 2016 (in other words, there is upside to our estimates should Eagle's other products reach the market). We believe a multiple of 17x is appropriate for Eagle based on an analysis of comparable companies in the broader generics space. The average 2016 P/E for this group is 17x and we believe a P/E in line with the generics group is appropriate. On one hand, there is the reality of litigation risk and the uncertainty over the timing of generic launches. On the other hand, EGRX has characteristics (e.g., the dantrolene EHS opportunity) that are in keeping with traditional brand specialty pharma companies (which typically trade at higher multiples compared to generics companies). The discount rate of 20% is, in our view, an appropriate reflection of the mix of clinical, regulatory, litigation and competitive risks associated with Eagle's key product opportunities.

We note that our valuation conclusion is supported by our 10-year discounted cash flow analysis (refer to Exhibit 2 below). Our discounted cash flow (DCF) analysis reflects contribution from EGRX's bendamustine and dantrolene products, as well as top-line contribution from other 505(b)(2) filings starting in 2021.

Exhibit 1

## PEER GROUP VALUATION ANALYSIS

(\$M except per share and multiples)				Market	Ent.	EPS			P/E			Revenue			EV/Revenue		
Ticker	Company	Rating	Price <sup>(1)</sup>	Cap	Value	2014E	2015E	2016E	2014E	2015E	2016E	2014E	2015E	2016E	2014E	2015E	2016E
TEVA	Teva	N	\$49.30	\$46,758	\$57,911	\$4.56	\$4.52	\$4.50	10.8x	10.9x	11.0x	\$1,994	\$19,772	\$19,598	NM	2.9x	3.0x
ACT	Actavis	O	\$213.18	\$37,136	\$43,073	\$13.03	\$14.63	\$15.75	16.4x	14.6x	13.5x	\$10,436	\$10,727	\$11,244	4.1x	4.0x	3.8x
PRGO	Perrigo	NR	\$164.48	\$21,999	\$24,692	\$6.63	\$7.94	\$9.22	24.8x	20.7x	17.8x	\$4,121	\$4,626	\$4,977	6.0x	5.3x	5.0x
MYL	Mylan	NR	\$54.86	\$20,403	\$26,838	\$3.45	\$3.86	\$4.15	15.9x	14.2x	13.2x	\$7,928	\$8,362	\$8,689	3.4x	3.2x	3.1x
HSP	Hospira	NR	\$43.35	\$7,216	\$8,259	\$2.13	\$2.29	\$2.68	20.4x	18.9x	16.2x	\$4,190	\$4,299	\$4,561	2.0x	1.9x	1.8x
MNK	Mallinckrodt	O	\$68.13	\$3,963	\$4,595	\$2.79	\$2.82	N/A	24.4x	24.2x	N/A	\$2,213	\$2,240	N/A	2.1x	2.1x	N/A
AKRX	Akorn	O	\$22.45	\$2,168	\$2,243	\$0.81	\$1.10	\$1.33	27.7x	20.4x	16.9x	\$534	\$641	\$700	4.2x	3.5x	3.2x
IPXL	Impax	O	\$27.45	\$1,915	\$1,501	\$0.68	\$0.82	\$1.21	NM	33.5x	22.7x	\$533	\$552	\$612	2.8x	2.7x	2.5x
LCI	Lannett	NR	\$44.25	\$1,551	\$1,396	\$1.85	\$2.08	\$2.18	23.9x	21.3x	NA	\$280	\$320	\$358	5.0x	4.4x	3.9x
SGNT	Sagent	O	\$21.61	\$687	\$541	\$0.13	\$0.72	\$0.97	NM	30.0x	22.3x	\$273	\$322	\$380	2.0x	1.7x	1.4x
Average - Eagle Peer Group									20.5x	20.9x	16.7x				3.5x	3.2x	3.1x
EGRX	Eagle	O	\$14.92	\$208	\$153	(\$1.53)	(\$1.84)	\$2.49	NM	NM	6.0x	\$7	\$9	\$144	NM	17.1x	1.1x

Source: PJC estimates, FirstCall, Bloomberg, and company reports

(1) Prices are as of March 7, 2014

Note: Bold denotes coverage companies for David Amsellem

Exhibit 2

DISCOUNTED CASH FLOW (DCF) ANALYSIS

\$ in millions, except per share	12/31/14	12/31/15	12/31/16	12/31/17	12/31/18	12/31/19	12/31/20	12/31/21	12/31/22	12/31/23
<u>Revenue</u>										
Bendamustine 505(b)(2) generic sales	\$0.0	\$0.0	\$131.2	\$83.3	\$64.4	\$56.1	\$53.3	\$50.6	\$48.1	\$45.7
Dantrolene - MH	\$0.0	\$6.0	\$10.2	\$17.3	\$22.4	\$24.8	\$26.7	\$28.0	\$29.4	\$30.9
Dantrolene - EHS	\$0.0	\$0.0	\$0.0	\$48.2	\$81.1	\$100.4	\$120.5	\$144.6	\$171.4	\$197.1
Bivalirudin 505(b)(2) generic sales	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$40.0	\$25.0	\$17.5	\$15.0
Pemetrexed 505(b)(2) generic sales	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$25.0	\$15.0	\$7.5	\$5.0
Miscellaneous generic sales								\$15.0	\$18.0	\$21.6
Argatroban royalties	\$6.5	\$3.0	\$2.5	\$2.0	\$2.0	\$2.0	\$1.9	\$1.8	\$1.7	\$1.6
Other revenue	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total revenue</b>	<b>\$6.5</b>	<b>\$9.0</b>	<b>\$143.9</b>	<b>\$150.8</b>	<b>\$169.8</b>	<b>\$183.3</b>	<b>\$267.4</b>	<b>\$280.1</b>	<b>\$293.6</b>	<b>\$316.9</b>
COGS	\$3.3	\$3.0	\$49.7	\$46.5	\$52.6	\$54.7	\$74.9	\$77.0	\$79.3	\$84.0
R&D	\$14.6	\$16.0	\$16.5	\$17.0	\$17.5	\$17.5	\$16.6	\$15.8	\$15.0	\$14.3
SG&A	\$8.9	\$17.2	\$20.0	\$25.0	\$32.0	\$37.5	\$41.3	\$42.5	\$43.5	\$44.4
Amortization and other expense	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Operating income</b>	<b>(\$20.3)</b>	<b>(\$27.2)</b>	<b>\$57.7</b>	<b>\$62.3</b>	<b>\$67.7</b>	<b>\$73.6</b>	<b>\$134.7</b>	<b>\$144.8</b>	<b>\$155.8</b>	<b>\$174.3</b>
<u>Free Cash Flow Calculation</u>										
<b>Operating Income</b>	<b>(\$20.3)</b>	<b>(\$27.2)</b>	<b>\$57.7</b>	<b>\$62.3</b>	<b>\$67.7</b>	<b>\$73.6</b>	<b>\$134.7</b>	<b>\$144.8</b>	<b>\$155.8</b>	<b>\$174.3</b>
Income Taxes	\$0.0	\$0.0	\$0.0	(\$3.1)	(\$13.6)	(\$22.1)	(\$47.1)	(\$50.7)	(\$54.5)	(\$61.0)
Depreciation	\$1.0	\$1.0	\$1.0	\$1.0	\$1.0	\$1.0	\$1.0	\$1.0	\$1.0	\$1.0
Capital Expenditures	(\$0.8)	(\$0.8)	(\$0.8)	(\$0.8)	(\$0.8)	(\$0.5)	(\$0.5)	(\$0.3)	(\$0.3)	(\$0.3)
Net Changes in Working Capital	\$5.7	(\$10.7)	(\$0.4)	(\$0.9)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Unlevered Free Cash Flow</b>	<b>(\$14.4)</b>	<b>(\$37.7)</b>	<b>\$57.5</b>	<b>\$58.5</b>	<b>\$54.3</b>	<b>\$52.0</b>	<b>\$88.0</b>	<b>\$94.8</b>	<b>\$102.0</b>	<b>\$114.0</b>
<b>Sum of Free Cash Flows</b>	\$569.0									
Discount Rate	20%									
Terminal Growth Rate	5%									
<b>Terminal Value</b>	<b>\$797.8</b>									
	12/31/14	12/31/15	12/31/16	12/31/17	12/31/18	12/31/19	12/31/20	12/31/21	12/31/22	12/31/23
Discount periods (years)	0.8	1.8	2.8	3.8	4.8	5.8	6.8	7.8	8.8	9.8
<b>Present Value of Free Cash Flows</b>	<b>\$152.3</b>	<b>(\$12.4)</b>	<b>\$34.4</b>	<b>\$29.2</b>	<b>\$22.6</b>	<b>\$18.0</b>	<b>\$25.4</b>	<b>\$22.8</b>	<b>\$20.4</b>	<b>\$19.0</b>
<b>Present Value of Terminal Value</b>	<b>\$133.2</b>									
<b>Eagle Market Value</b>	<b>\$285.5</b>									
Diluted shares outstanding (MM)	13.9									
<b>Eagle Market Value per Share</b>	<b>\$21</b>									

Source: PJC Research and company reports

## RISKS TO OUR THESIS

**FDA and clinical trial risk.** Eagle's regulatory risks are generally similar to those of its other specialty pharma peers. Its generic products, like bendamustine, have minimal approval risk. However, dantrolene is a brand opportunity. Since the old version of dantrolene is already approved for malignant hyperthermia (MH), approval risk in this setting should be limited. That said, exertional heat stroke (EHS) would be a new use of the product, and Eagle is running a Phase III study in this setting. As such, there is always the possibility that the trial fails, though we would keep in mind that MH and EHS are essentially similar conditions, potentially mitigating the clinical risk in the EHS setting.

**Legal risks.** Though Eagle's generics are not traditional, aNDA-based generics, the companies that distribute the predecessor, innovator products will nonetheless claim that Eagle infringes on their intellectual property and will pursue litigation. This is already the case in the matter of bendamustine, and will likely be the case for most, if not all, of Eagle's other generic filings. As such, there is the risk that the courts will determine that Eagle infringes on patents protecting the innovator products, preventing Eagle from launching its generics. That said, we would keep in mind that Eagle's formulations of these generics are different (in other words, it is the same underlying molecule but a different, typically optimized, way of delivering said molecule). Further, many of the generics that Eagle is pursuing are protected by relatively thin and narrow patents (such as patents on the formulations of the innovator products; this is bearing in mind that Eagle is developing different formulations). As such, Eagle is positioning itself so that it does not infringe on innovator patents. That said, brand companies are sophisticated, and there is always the risk that they will succeed in their litigation.

**Competition, both from brands and generics.** Eagle is aiming to bring its generics to market ahead of other generic companies that are making conventional copies of brand products. The timing of additional competition on products like bendamustine is uncertain, and if Eagle does not succeed in its litigation, it may be entering markets along with several other generic competitors (meaning pricing pressure and more limited margins).

## UPCOMING EVENTS AND MILESTONES

Exhibit 3

## EAGLE CALENDAR OF UPCOMING EVENTS

Product/ Program	Event	Expected Date
Bendamustine	PDUFA date for ready-to-dilute (RTD) product (EP-3101)	July 6, 2014
Bendamustine	Potential summary judgement in litigation versus Teva	Mid-2014
Dantrolene	Potential FDA approval in MH	4Q14
Dantrolene	Potential initiation of pivotal trial for heat stroke	late 2014/early 2015
Bendamustine	Submit sNDA for RTD, shorter infusion time formulation (EP-3102)	1Q15
Bivalirudin	Possible NDA submission	2Q15
Dantrolene	Possible data from pivotal trial for heat stroke	mid-to-late 2015

Source: Company reports and PJC Research

Exhibit 4

## EAGLE PHARMACEUTICALS PRODUCT PIPELINE

Drug name (description)	US Branded Reference Drug	2013 Branded Sales (\$M)	Clinical/Regulatory Status
EP-3101 (bendamustine RTD)	Treanda	\$681	NDA submitted; July 6, 2014 PDUFA date
EP-3102 (bendamustine short infusion time)	Treanda	\$681	Pivotal trial ongoing
Ryanodex (dantrolene)	Dantrium	\$20	NDA submitted in 1Q14; Orphan drug designation received
EP-4104 (dantrolene)	Dantrium	No approved drug for EHS	Orphan designation received for EHS
EP-6101 (bivalirudin)	Angiomax	\$464	Type C meeting with the FDA completed in 4Q13
EP-5101 (pemetrexed)	Alimta	\$1,197	Formulation work complete
EP-1101 (argatroban)	Argatroban	\$79	Approved in the U.S.; marketed by MDCO and Sandoz
EP-2101 (topotecan)	Hycamtin	\$18	Approved in the E.U.; not marketed

Abbreviations RTD ready to dose

Source: Company reports, IMS Health and PJC Research



## FINANCIAL OVERVIEW

**Expectations for bendamustine.** Our model reflects an early 2016 launch of EGRX's bendamustine generic, with estimated sales of \$131 million for the product in the launch year. We assume that EGRX launches its product ahead of competition from traditional aNDA filers (more on our market assumptions for EGRX's bendamustine below). As competition from aNDA generics materializes (potentially as 2016 progresses, bearing in mind that the first 30-month stay expiries for aNDA filers begin in April 2016), we model bendamustine sales falling to \$64 million by 2018. Though the generic bendamustine market over time could become crowded (i.e., pointing to significant price erosion), we would keep in mind that usage of the product continues to grow, and that EGRX, with a differentiated product (i.e., a product with a shorter infusion time), should enjoy meaningful volume share in our view. In that sense, we believe that trough annual bendamustine sales for EGRX should be no worse than roughly \$40-\$50 million.

**Expectations for dantrolene.** Regarding dantrolene (proposed trade name of Ryanodex), our model reflects an early 2015 launch of the product in MH, with sales of \$6 million in the launch year, growing to \$10 million in 2016. EGRX submitted its filing on dantrolene in January 2014. Our model reflects the conversion of most of the MH market to EGRX's more convenient formulation. Over the longer-term, we would not be surprised to see pricing power in the MH setting given the advantages of EGRX's product and the reality that hospitals must stock the product given the dire nature of MH. Our model reflects sales in MH of \$25 million in 2019, bearing in mind that the current annual market size is closer to \$20 million. Regarding the exertional heat stroke opportunity, we are modeling a label expansion for dantrolene in 2017, with sales of \$48 million in the launch year, growing to \$100 million in 2019.

**Margins and expenses.** We are modeling gross margins of 67% in 2015, reflecting the impact of dantrolene in MH (only modest sales but relatively low manufacturing costs in a space with limited competition). With bendamustine launching in 2016, we model gross margins falling slightly to 65% for the year. The relatively healthy gross margins (at least for a generics-focused company) reflects the period of time in 2016 that EGRX has exclusivity on bendamustine (bearing in mind that gross margins for a generic product that has exclusivity are often brand-like). For 2017, our model reflects gross margins expanding slightly to near 70%, reflecting the impact of the expanded label for dantrolene (i.e., brand pricing), but with lower margins on bendamustine due to the impact of additional competition. Given the contribution from dantrolene and the reality that manufacturing costs on bendamustine are limited, we expect that EGRX will be able to enjoy gross margins that are higher than traditional generics companies. For instance, Akorn (AKRX), which is focused on higher barrier to entry generics (namely ophthalmics and injectibles), had corporate gross margins of 54% in 2013 (and there is only modest contribution from brand products).

Regarding operating expenses, our model reflects the build out of a U.S. commercial organization comprised of around 40 reps. The sales organization will focus on hospitals and infusion centers. Our SG&A expense estimate is \$17 million in 2015, ramping to \$20 million in 2016 and \$25 million in 2017 (this is compared to only \$4 million in 2013). We are modeling further growth in SG&A beyond 2017 as EGRX adds additional infrastructure to support the ramp of dantrolene in EHS. This is bearing in mind that EGRX will be focusing not only on hospitals, but communities as well (i.e., first responders, schools). Regarding R&D, our estimates for 2014-2016 range between \$15 million and \$17 million. We expect R&D expenses to grow only gradually in later years as EGRX advances other 505(b)(2)

opportunities (but other development programs that EGRX completes will to large extent offset these new costs).

**Profitability should come quickly if EGRX can launch on bendamustine ahead of the aNDA crowd.** We estimate that EGRX will achieve full-year profitability in 2016 with the launch of bendamustine. As competition on bendamustine intensifies in 2017 and beyond, we expect more modest profitability compared to 2016, though increasing contribution from dantrolene in EHS which should enable a relatively stable stream of earnings (and as bendamustine reaches its nadir, the growth of dantrolene should enable meaningful earnings growth; this type of “lumpy” cash flows are not uncommon for generics companies). Our model does not reflect any contribution from other 505(b)(2) opportunities. Our diluted EPS estimate in 2016 is \$2.49, declining to \$2.03 in 2019 (but stabilizing and then growing thereafter).

**Balance sheet.** As of December 30, 2013, EGRX had \$10.0 million in cash and cash equivalents. EGRX received net proceeds of \$47 million from its recent initial public offering (on 2/12/14). Our estimates reflect only a modest additional capital raise in 2015 (of around \$20 million), though that may not be necessary should EGRX choose to table additional development programs until it is generating cash flows from bendamustine (in other words, our model reflects fairly aggressive R&D spend in order for EGRX to build out its portfolio of 505(b)(2) filings).

#### Exhibit 5

#### SUMMARY OF PJC ESTIMATES FOR EGRX

\$ in millions, except per share	2014E	2015E	2016E	2017E	2018E	2019E
<i>Revenue</i>						
Bendamustine generic sales	\$0.0	\$0.0	\$131.2	\$83.3	\$64.4	\$56.1
Dantrolene - MH	\$0.0	\$6.0	\$10.2	\$17.3	\$22.4	\$24.8
<b>Total revenue</b>	<b>\$6.5</b>	<b>\$9.0</b>	<b>\$143.9</b>	<b>\$150.8</b>	<b>\$169.8</b>	<b>\$183.3</b>
<i>Expenses</i>						
COGS	\$3.3	\$3.0	\$49.7	\$46.5	\$52.6	\$54.7
R&D	\$14.6	\$16.0	\$16.5	\$17.0	\$17.5	\$17.5
SG&A	\$8.9	\$17.2	\$20.0	\$25.0	\$32.0	\$37.5
Operating income	(\$20.3)	(\$27.2)	\$57.7	\$62.3	\$67.7	\$73.6
non-GAAP Net Income	(\$20.9)	(\$27.8)	\$57.7	\$59.4	\$54.3	\$51.7
<b>non-GAAP EPS, diluted</b>	<b>(\$1.53)</b>	<b>(\$1.84)</b>	<b>\$2.49</b>	<b>\$2.48</b>	<b>\$2.20</b>	<b>\$2.03</b>
Shares outstanding, diluted	13.6	15.1	23.2	23.9	24.7	25.4

Source: Company reports and PJC Research

## COMPANY BACKGROUND

Eagle is focused on optimizing injectable drugs targeted for use within the hospital and outpatient infusion centers. The company's pipeline is concentrated on products that will utilize the FDA's 505(b)(2) pathway to market (as opposed to the traditional abbreviated NDA pathway for generics). This is a pathway for a generic drug in the institutional setting that is advantageous in our view given that traditional substitutability in this setting is not nearly as crucial to gaining volume share compared to the retail pharmacy setting.

**Optimized generics provides competitive advantages and a pathway to sustainable cash flows.** Eagle's overarching goal is to making incremental but potentially value-added improvements to the innovator product (e.g., shorter infusion times that translate into pharmacoeconomic benefits). The filing pathway will have a standard 10-month FDA review, per the Prescription Drug User Fee Act (PDUFA), enabling EGRX to gain approvals far quicker than the timeline associated with traditional generics. Further, by making modifications to the innovator product, EGRX can more readily maneuver around innovator intellectual property. These dynamics could result in EGRX bringing its products to market ahead of traditional aNDA-based generics. Lastly, by offering customers an optimized generic product, EGRX can position itself for strong volume share even in the face of significant competition from traditional generics (bearing in mind that EGRX will price its products essentially as a traditional generic as opposed to a employing a brand-like pricing strategy).

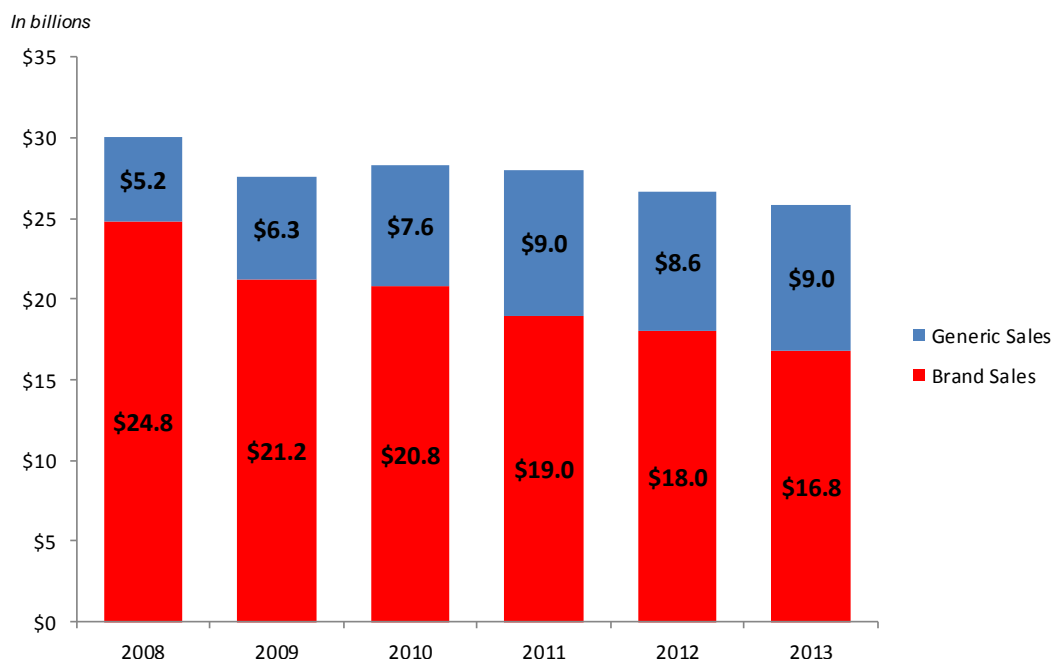
Eagle currently has two late-stage development programs: a more efficient and easier-to-administer formulation of the oncology drug Treanda and an optimized formulation of dantrolene, which Eagle will pursue approval for both malignant hyperthermia (MH) and exertional heat stroke (EHS). Regarding dantrolene in EHS, this is an example of how Eagle can also use its business model to develop more traditional brand assets that are used in institutional settings (i.e., enhanced brand formulations are ubiquitous in pharma, in both the retail pharmacy and institutional settings), and in this case, EGRX has orphan status for both indications. EGRX also has a number of injectible product candidates in its pipeline, and we expect a number of additional 505(b)(2) filings in the coming years.

## THE HOSPITAL INJECTIBLES SPACE, IN BRIEF

According to IMS Health, the U.S. generic injectibles market has annual sales north of \$9 billion in 2013, up from just over \$5 billion in 2008. A significant majority of these products are sold into hospitals. The vast majority of hospital spending on drug products (around 90%-95%) is on injectibles and other non-oral formulations. That said, most hospital expenditures on injectible products come from spending on branded drugs, which accounts for 65% of spending on injectibles. Total sales of branded injectible products (excluding biologics) were just under \$17 billion in 2013, down from almost \$25 billion in 2008.

Exhibit 6

### SUMMARY OF BRAND AND GENERIC NON-BIOLOGIC INJECTIBLE DRUG SALES IN THE U.S



Source: IMS Health and PJC Research

**The generic injectibles space is not overly crowded.** Given the complexity associated with manufacturing injectibles relative to oral solids (i.e., the complexities of sterile manufacturing at a minimum), there are far fewer generics companies that have capabilities in this segment compared to garden variety oral solids. The capital requirements are simply more onerous, and maintenance capital expenditures are significantly greater for an injectibles facility than they are for facilities that make solid dosage forms. In that vein, it is not surprising that there are relatively few emerging companies in the space. Given that the space is not particularly crowded, price destruction need not necessarily be a pitfall for all generic injectible products. In other words, even for older injectible products, commoditization often does not occur, and that has especially been the case in recent years given the widespread product shortages that have emerged due to manufacturing problems at a number of sites.

The largest companies in the U.S. generic injectible market include Hospira, Sandoz, and APP (in terms of 2013 sales, according to IMS). Interestingly, over half of the generics approved between 2003 and 2008, according to data from Espicom Business Intelligence, had only one or two generic entrants and over 85% of the injectibles had less than five generic competitors.

**Barriers to entry tend to be high.** Generally speaking, the generic injectibles segment has a number of barriers to entry. These include formulation and development hurdles, scarcity of raw materials, scarcity of vial components, complex sterilized manufacturing requirements, and more sophisticated packaging (such as pre-filled syringes). Purchasing for hospitals is often negotiated through Group Purchasing Organizations (GPOs) that generally contract for products for a year at a time. The GPOs prefer to make their purchases from well established suppliers that have a history of meeting their supply quotas with stable volumes. Given that many of these products are used in acute treatment settings and critical care settings, GPOs will generally do business with generic companies that have well-established capabilities who can provide a steady stream of uninterrupted supply of products.

Given that the space is relatively capital intensive, it is not surprising that companies looking to enter the injectibles space are largely doing so via acquisition rather than building its own infrastructure. We have seen a number of notable acquisitions of injectible companies in recent years. Notable M&A activity in the generic injectibles space includes Fresenius' acquisition of APP in 2007 for \$3.7 billion, Sandoz's acquisition of Ebewe in 2009 for \$1.2 billion, Mylan's acquisition of Bioniche in 2010 for \$550 million, and Hikma's acquisition of Baxter's injectibles unit in 2010 for \$112 million, to name a few.

**Well over \$5 billion worth of non-biologic injectible sales that will go off patent in the next 5 years (or are off patent but do not yet have generic competition).** Exhibit 7 below provides a detailed overview the top brand injectible drugs (excluding biologics) in the U.S. Though we would not focus too much on brands coming off patent since demand for many older injectibles that went generic years ago is strong and commodization tends to be rare, we would point out that the sizeable number of brands that are off patent or going off patent points to continued strong growth in volumes for the generic injectibles space. We note that Eagle's pipeline consists of 505(b)(2) generics for three of the top brand injectibles on the list below.

## Exhibit 7

**TOP BRAND INJECTIBLE DRUGS (NON-BIOLOGICS) IN THE U.S.**

Product	Generic name	Manufacturer	Patent expiry	2013 IMS Sales (\$M)
Copaxone	glatiramer	Teva	May 2014	\$3,711
Alimta	pemetrexed	Eli Lilly	May 2022	\$1,197
Treanda	bendamustine	Teva	April 2016 <sup>(1)</sup>	\$681
Cubicin	daptomycin	Cubist	September 2019	\$632
Lexiscan	regadenoson	Astellas	February 2027	\$549
Aloxi	palonosetron	Eisai	January 2024	\$469
Angiomax	bivalirudin	Medicines Co.	January 2029	\$464
Lovenox	enoxaparin	Sanofi	Generics available	\$352
Venofer	iron sucrose	Luitpold	Patents expired	\$321
Precedex	dexmedetomidine	Hospira	January 2014	\$278

Source: Company reports, IMS Health, FDA Orange Book, and PJC Research

<sup>(1)</sup> Refers to expiration of orphan drug exclusivity; latest Orange Book listed patent expires in October 2030

Note: Patent expiry refers to the last relevant Orange Book listed patent to expire and in some cases reflects pediatric extensions

**THE 505(B)(2) PATHWAY: A LOGICAL APPROACH TO GENERIC INJECTIBLES**

There are three types of new drug applications (NDA) that can be submitted to the FDA by a sponsor seeking to market a non-biologic pharmaceutical product. The first is what we can call a traditional NDA, or full NDA, which is generally used for novel new drugs to be marketed as brand pharmaceutical products. Per section 505(b)(1) of the the Federal Food, Drug and Cosmetic Act, a full NDA is “*an application used for approval of a new drug (for clinical use) whose active ingredient has not previously been approved,*” and that this type of application “*contains full reports of investigations of safety and effectiveness.*” The traditional NDA is also frequently referred to as an NDA filed via the 505(b)(1) pathway. At the other end of the spectrum, a 505(j) NDA, or what is more frequently known as an abbreviated NDA (aNDA), is an application used for approval of a “generic” version of a drug that has already been approved. In this type of application, the filing contains information to demonstrate that the proposed generic version is identical to a previously approved product. This can be achieved in most cases simply through chemistry and bioequivalence data, without the need for clinical trials to assess the proposed generic’s safety and efficacy. Somewhere in the middle of the traditional NDA and the aNDA is an NDA filing submitted via what is known as the FDA’s 505(b)(2) pathway. This type of filing allows the applicant to rely, at least in part, on the FDA’s findings of safety and/or effectiveness for a previously approved drug (i.e., the “reference drug”). This pathway can be used for a wide range of proposed products, including changes in dosage form, route of administration, formulation, dosing regimen, dosage strength, or indication relative to the reference drug.

The traditional approach to building a pipeline and commercial portfolio of generic versions of injectible products is via the aNDA pathway. Numerous companies have built out large injectible generics businesses utilizing this pathway, including market leaders Hospira (HSP) and APP. Eagle's strategy is to utilize the 505(b)(2) regulatory pathway to commercialize optimized, or differentiated, versions of injectible products already on the market. These proposed product enhancements include improvements to the preparation and administration process, longer shelf life, and shorter infusion times.

**A faster timeline to commercialization.** One of the key advantages to the 505(b)(2) pathway relative to aNDAs is that 505(b)(2) applications are subject to PDUFA and therefore have review periods that are in keeping with the review periods for traditional NDAs (a review period of 10 months or 6 months for filing that has priority review status). In contrast, the average review timeline for an aNDA filing is now well north of 30 months from the filing date. In that context, the 505(b)(2) strategy theoretically offers almost a two year head start over aNDA-based generic filings. However, we note that if the reference listed product has unexpired intellectual property (IP) listed in the FDA's Orange Book, the launch of both a 505(b)(2) product and an aNDA product are likely to be subject to a 30-month legal stay if the maker of the reference listed drug chooses to initiate patent litigation. In other words, the FDA cannot grant final approval to a filing during this 30 month stay. That said, if the litigation is closed via a summary judgment or district court ruling in favor of the generic challenger within this 30 month legal stay, the challenger is of course allowed to launch its product once approved. In this scenario, if the challenger that filed its product via the 505(b)(2) pathway prevails in the litigation and receives a timely FDA approval, it could launch ahead of aNDA-based generics and enjoy a period of generic exclusivity. Further, having a 505(b)(2) filing may enable greater maneuverability around innovator IP given that the filer in this case is not claiming "sameness," and in some cases, innovator IP is fairly narrow. In short, that dynamic opens up the possibility that the 505(b)(2) filer could prevail in its litigation with the aNDA filers losing in court, opening up the potential for a prolonged period of generic exclusivity. Lastly, even if a 505(b)(2)-based product enters the market at the same time, or slightly after, the first aNDA-based generic, the 505(b)(2)-based product would be able to enter the market even if the aNDA filer has the right to 180 days of generic exclusivity (in other words, the 180-day period of exclusivity under Hatch-Waxman only applies to aNDA filers).

**Eagle's argatroban serves as an early validating event.** Eagle pursued the 505(b)(2) regulatory pathway for its optimized formulation of the cardiac injectible argatroban, receiving FDA approval for its product in June 2011 (Eagle is partnered with The Medicines Company for the product). The formulation was different from the innovator product in that it does not need to be diluted and was formulated in a way so that it reduces drug waste relative to the innovator product. In addition to optimizing the product, EGRX's goal was also to design a product that avoided infringement of the brand's Orange Book listed patents (in this case, the innovator is GlaxoSmithKline). GSK did not sue Eagle for patent infringement. Upon approval of its product, the EGRX formulation became commercially available and became the first generic version of argatroban on the market. At one point, the product had close to 30% of the volume of this near \$100 million annual market. Traditional aNDA filers for the product were not able to demonstrate invalidity or non-infringement of the GSK patents, and therefore have to wait until June 2014 (when the last Orange Book patent expires) before its products can launch. In this case, Eagle achieved a two year head start versus aNDA-based generics.

Exhibit 8

## SUMMARY OF FDA DRUG PRODUCT REGULATORY APPLICATIONS

	Abbreviated NDA (aNDA)	Traditional NDA	505(b)(2) NDA
<b>Section of the Federal Food, Drug and Cosmetic Act that governs its use</b>	Section 505(j)	Section 505(b)(1)	Section 505(b)(2)
<b>Clinical work required</b>	Only bioequivalence studies for vast majority of filings	Full blown, well controlled clinical trials	Clinical trials needed to address potential differences between the branded reference product and the 505(b)(2) product. In certain cases, only bioequivalence studies need to be conducted
<b>FDA review period</b>	Average of over 30 months	10 months (6 months for priority review)	10 months (6 months for priority review)
<b>Potential for Orange Book listed patents</b>	No	Yes	Yes
<b>Potential for Exclusivity</b>	Eligible for 180 days of exclusivity if first-to-file (FTF)	Potential for 5 years of exclusivity for a new chemical entity (NCE) or 3 years for new clinical investigations. Potential for 30-month stay for Orange Book-listed patents	Potential for 3 years for new clinical investigations. Potential for 30-month stay for Orange Book-listed patents
<b>Paragraph IV Certification</b>	Required	Not applicable	Required
<b>Potential for Orphan Drug status</b>	No	Yes	Yes

Source: Company reports, Industry reports and FDA.gov



**BENDAMUSTINE: A HIGH-VALUE OPPORTUNITY;  
NARROW IP GIVES EAGLE A FIGHTING CHANCE**

Bendamustine, marketed by Teva/Cephalon under the trade name Treanda, was approved by the FDA in chronic lymphocytic leukemia (CLL) in April 2008 and in Rituxan-refractory indolent non-Hodgkin's lymphoma (NHL) in November 2008. Treanda was discovered in the former East Germany in the 1960s and was used for a variety of hematologic malignancies including CLL, NHL and multiple myeloma. Sales of the brand as reported by Teva were \$709 million in 2013, up from \$608 million in 2012, and volumes for the product continue to grow.

**Teva continues to distribute its lyophilized form, but an approved liquid form is waiting in the wings.** The bendamustine formulation that was originally approved by the FDA is a lyophilized (i.e., freeze-dried) powder, which requires reconstitution with sterile water prior to infusion. Once reconstituted and ready for administration, the product is infused over 30 minutes in patients with CLL and for 60 minutes in patients with NHL. The need for reconstitution has several key drawbacks, particularly in the case of Treanda. When mixing the lyophilized powder with sterile water, there is always the potential for dosing errors (i.e., adding too little or too much of the diluent than directed by the label). There is also the potential for a significant amount of the product to be wasted, bearing in mind that Treanda must be infused within 30 minutes of the vial being opened. In September 2013, Teva received FDA approval for a new formulation of Treanda, which is a ready-to-use (i.e., no dilution) liquid concentrate (we note that both the liquid and lyophilized forms are infused over 30-60 minutes). Though Teva has yet to launch its new liquid formulation, we would expect to see a launch at some point, bearing in mind that all of the aNDAs on bendamustine are on the lyophilized form. In other words, it would make sense for Teva to stop supplying the market with the lyophilized form, effectuate a switch to its new liquid form, thereby forcing the aNDA filers to go back to the drawing board and file on the liquid form, or bring a generic version of the lyophilized form to market and fight for share bearing in mind that hospitals and infusion centers may not be motivated to switch back to a less convenient presentation. The current reality, however, is that Teva's liquid formulation is something of a wild card, though only for the aNDA filers, not for Eagle given that it is focused solely on a liquid form of bendamustine, with potential improvements over Teva's newly approved formulation.

**Eagle has two bendamustine shots-on-goal, each differentiated from Teva's forms of the product in our view.** Eagle is developing two new formulations of bendamustine. The first of Eagle's products (known as EP-3101) is an enhanced liquid formulation of bendamustine that has less degradation compared to Treanda (in other words, Eagle's product would reduce the potential for wasted drug, a key drawback of Treanda) and also will have a longer shelf life (stability after first use for EP-3101 is 28 days in vial, compared to 30 minutes for Treanda). Eagle's second product (known as EP-3102) is also a liquid formulation of bendamustine, but is designed to reduce the drug's infusion time to only 10 minutes. This product would help increase chair turnover in the infusion center, with the idea of providing meaningful pharmacoeconomic benefits to administrators. In short, Eagle believes its alternatives will offer key advantages over the predecessor drug, such as the reduction of wasted drug, more efficient work flow, and less infusion time for patients and handlers.

Exhibit 9

## SUMMARY OF BENDAMUSTINE PRODUCTS

	Treanda (powder)	Treanda (liquid)	EP-3101	EP-3102
<b>Company</b>	Teva	Teva	Eagle	Eagle
<b>Presentation form</b>	Lyophilized powder; 25 mg and 100 mg single-use vials	Liquid solution; 45 mg/0.5mL and 180mg/2mL	Liquid solution, 25mg/mL	Liquid solution
<b>Regulatory/commercial status</b>	Approved in March 2008; marketed by Teva	Approved in September 2013; not yet launched	NDA filed; PDUFA date 7/6/2014	Pivotal trial ongoing
<b>Requires reconstitution</b>	Yes	No	No	No
<b>Saline bag</b>	500 mL	500 mL	500 mL	50 mL
<b>Infusion time</b>	30 minutes in CLL patients; 60 minutes in NHL patients	30 minutes in CLL patients; 60 minutes in NHL patients	30 minutes in CLL patients; 60 minutes in NHL patients	10 minutes (proposed)
<b>Stability after first use</b>	30 minutes in vial	30 minutes in vial	28 days in vial	28 days in vial
<b>Patent protection</b>	Principal patents: #8,445,524 and #8,436,190	Patent #8,344,006 (Orange Book listed)	Several U.S. patent applications	Several U.S. patent applications

Source: Company reports, FDA.gov, and PJC Research

## Background on the Litigation with Teva and the Treanda '524 Patent

Upon filing its NDA for EP-3101 (which included a Paragraph IV certification) in September 2013, Teva/Cephalon initiated litigation against Eagle. Given the differences of its products versus the brand, Eagle believes it does not infringe on Treanda's patents. Teva has three patents listed in the FDA Orange Book with various claims surrounding the lyophilized powder form of bendamustine. In the ongoing litigation versus Eagle, Teva is currently defending one of these patents, specifically patent # 8,445,524 (the '524 patent), which expires in March 2029. Broadly speaking, the patent has claims surrounding a solid form of bendamustine, namely a crystalline polymorph. We note that a polymorphism is the ability of a solid (a crystalline structure) to exist in multiple forms. In drug development, researchers generally identify how many of these crystalline structures there are and identify which have the most optimal stability. The form and pattern is characterized using a technique called X-ray crystallography. Some polymorphs behave differently from one another, such as having different bioavailability and dissolution profiles. In other cases, differences among various polymorphs of a drug are not meaningful and would not confer any clinical relevance.

Our patent consultants noted that while the '524 patent has a number of independent claims, the patent essentially lives and dies on claim 1, which reads as follows:

*"A solid form of bendamustine hydrochloride, designated as bendamustine hydrochloride Form 1, that produces an X-ray powder diffraction pattern comprising the following reflections: 8.3, 16.8, and 18.5 +/- 0.2 degrees 2.theta.."*

On a simplistic level, the patent speaks exclusively to a specific polymorph. Recall that Eagle has a liquid formulation. According to our patent consultants, if Eagle can reliably show that its product did not exist as a solid structure, it should have a strong chance of demonstrating non-infringement. According to Eagle, it sources its active pharmaceutical ingredient (API) from Europe and its finished product is manufactured in India. In short, Eagle is claiming that it has a product that never existed in the U.S. in any way as a solid.

### Teva's Liquid Form of Bendamustine and Implications for Eagle

As previously mentioned, Teva does have a liquid form of bendamustine that gained approval in September 2013, though Teva has yet to launch the product. We are aware of one issued patent specifically covering the liquid formulation, patent #8,344,006 (the '006 patent), which was recently listed in the FDA's Orange Book. It is important to note that the '006 patent is a formulation patent that covers "stable liquid formulations of bendamustine." In the patent, claim 1 reads as follows:

*"A stable, non-aqueous liquid, pharmaceutical formulation comprising from about 5 mg/ml to about 120 mg/mL of bendamustine, or a pharmaceutically acceptable salt thereof, solubilized in about 66% (v/v) of dimethylacetamide and about 34% (v/v) of propylene glycol, wherein said formulation, following dilution with a pharmaceutically acceptable diluent, is suitable for injection into a patient without lyophilization."*

Interestingly, Eagle asserts that its bendamustine formulation uses different ingredients relative to Teva's formulation (as summarized in the '006 patent language) to make it stable in liquid. In other words, Eagle is asserting that it has engineered its product around this patent (at least in theory). Further, Eagle filed its NDA for EP-3101 prior to Teva gaining approval on its liquid form, so it does not have to certify under paragraph IV against Teva's recently listed '006 patent. Teva could of course sue Eagle on this patent, but Eagle would not be subject to a new 30-month stay.

We do not believe that Teva launching on its liquid form would be a negative for Eagle. In actuality, it may very well turn out to be a positive development for Eagle. As we note above, all of the other generic filers have filed abbreviated NDAs on the lyophilized form. Teva could easily switch over the market to its liquid form. We surmise that if Teva did launch on the liquid form, it would effectuate a "hard switch," meaning that it would no longer supply the market with the lyophilized form and only distribute the liquid (it would not make sense for Teva to launch on the liquid form and not do a hard switch given that all of the aNDAs are for the lyophilized form). Some or all of the aNDA filers could attempt to launch on the lyophilized form (more of an uphill battle to gain significant traction with the market having been switched over), or simply submit new filings on the liquid, thereby restarting the FDA review clock. If Eagle were to show non-infringement on the '524 patent and launch its product, we could envision a plausible scenario where Teva and Eagle essentially share the Treanda market for a prolonged period while the aNDA filers go back to the drawing board and file applications on Teva's liquid form (to be clear, that is not a scenario that is reflected in our estimates).

Treanda's orphan disease exclusivities also could mean a 2Q16 launch at the earliest for EGRX, but a potential work-around Teva's orphan protection bears watching. Treanda has orphan drug exclusivity for NHL through October 2015, and also gained another six months of pediatric exclusivity that extends orphan protection through April 2016. For CLL, Treanda has orphan drug exclusivity until September 2015, including six months of pediatric exclusivity. As such, the FDA may be precluded from issuing final approval of EGRX's filings for its bendamustine products for these indications until these exclusivities expire.

EGRX is seeking to work around Teva's orphan status. It is our understanding that a product filing can be approved and launched prior to the expiration of the reference listed drug's orphan drug exclusivity if it fulfills at least one of the three criteria: (1) the product shows a clinical benefit over the reference listed drug; (2) the product shows a safety benefit over the reference listed drug; or (3) the product shows a major benefit to patient care relative to the reference listed drug. On the latter point, we believe that EGRX has a plausible chance of demonstrating to the FDA that EP-3102's short infusion time could be classified as a major benefit to patient care.

Exhibit 10

## OVERVIEW OF KEY TREANDA PATENTS

Patent #	Title	Abstract	Expiration date	Claims summary	Litigation status
8,445,524	"Solid forms of bendamustine hydrochloride"	"Novel solid forms of bendamustine hydrochloride are described, as well as methods of their preparation and use."	3/26/2029	Main claims related to Form 1 polymorph	Asserted against Eagle; asserted against aNDA filers
8,436,190	"Bendamustine pharmaceutical compositions"	"The present invention provides pharmaceutical formulations of lyophilized bendamustine suitable for pharmaceutical use. The present invention further provides methods of producing lyophilized bendamustine. The pharmaceutical formulations can be used for any disease that is sensitive to treatment with bendamustine, such as neoplastic diseases."	10/26/2030	Main claims related to lyophilized compositions of bendamustine	Not asserted against Eagle; asserted against aNDA filers
8,344,006	"Liquid formulations of bendamustine"	"Stable liquid formulations of bendamustine, and pharmaceutically acceptable salts thereof, and polar aprotic solvents, are described."	9/23/2029	Main claims related to liquid compositions of bendamustine	Not asserted against Eagle and not part of 30-month stay

Source: Company reports, USPTO, FDA.gov, and PJC Research

Note: Patent expirations do not include the potential for a 6-month pediatric extension

### A Wide Range of Bendamustine Scenarios For EGRX, but A Very Real Chance of A Launch Ahead of Vanilla Generics

Depending on the timeline and outcome of the litigation, Eagle believes it could be in position to launch its bendamustine product(s) as early as 4Q14 or as late as March 2016 (the expiry of its 30-month legal stay). This timeline is important given that, to our knowledge, there are at least 9 aNDA generic filers on the lyophilized powder formulation of Treanda (though the lyophilized market may be obsolete given that Teva most likely will convert the market to the liquid form; that said, some of these generic filers could elect to launch on their lyophilized form). The 30-month legal stay for most these traditional abbreviated NDA filers will likely be in mid-2016 (and this is the earliest these generics could launch). This framework provides Eagle with a minimum of around three months of exclusivity (i.e., the only generic, and an “optimized” one at that) for its bendamustine product. Beyond that however, given that the other generics will have only the lyophilized form, this is a market that is unlikely to be highly competitive in 2016. In other words, we could see generic filings on Teva’s liquid form later this year, meaning that the timeline to the potential launch of aNDA-based generic versions of the liquid form will likely be 2017 at the earliest (bearing in mind that the filers will have to certify under paragraph IV on the ‘006 patent). As such, we believe there is potentially a wide window where Eagle’s product could capture a significant chunk of bendamustine volumes.

In Exhibit 11 below, we provide a brief summary of how the extent of competition on bendamustine translates into annual sales for EGRX, irrespective of when EGRX can launch its product (in other words, we are only measuring the variable impact of competition on potential sales to EGRX). The larger point here is that though there is significant uncertainty on the extent of competition (i.e., will generic filers on the lyophilized product launch even if Teva switches over the market?; how many generic filings will we see on Teva’s liquid form?), most scenarios still point to meaningful sales for EGRX.

Exhibit 11

#### EAGLE’S BENDAMUSTINE SALES FOR VARYING DEGREES OF COMPETITION

Treanda annual brand sales	# of generics (including EGRX)	Price discount to Teva’s brand	Dollar value of bendamustine market	Estimated EGRX market share	Estimated bendamustine sales to EGRX
\$875	EGRX exclusive	20%	\$700	50%	\$350
\$875	3	45%	\$481	45%	\$217
\$875	6	80%	\$175	35%	\$61
\$875	9	90%	\$88	30%	\$26

Source: Company reports and PJC Research

### What Does a Plausible Base Case for EGRX Look Like?

As outlined above, given the uncertainty regarding when EGRX will be able to launch its bendamustine product and the extent of competition from traditional aNDA filers EGRX may face (and when), the possible sales potential for EGRX's bendamustine encompasses a very wide range. That said, a realistic scenario, in our view, is a launch of EGRX's product just after the expiry of the 30-month legal stay and Teva's orphan status (i.e., a 2Q16 launch). Below we outline our assumptions regarding our base case scenario:

- **Underlying bendamustine market.** We estimate that annual U.S. sales of Teva's brand should be near \$875 million by the time competition materializes from EGRX (i.e. sometime in 2016).
- **Launch timing.** In our base case, we conservatively assume that the lower court does not grant summary judgement (this is generally pretty rare) sometime later this year. Rather, we assume that the case goes to trial and that EGRX demonstrates non-infringement. Our model assumes that EGRX launches in 2Q16 (specifically May 2016), and is the only generic on the market at launch.
- **Market share.** We assume EGRX's product enjoys at least a few months of exclusivity prior to traditional aNDA generics entering the market. This may be an overly conservative assumption (i.e., that some generic filers demonstrate non-infringement) given that generics on the lyophilized form may have a more difficult time demonstrating non-infringement (i.e., after all, Teva's Orange Book patents have various claims surrounding solid forms of bendamustine). That said, we nonetheless assume that there are additional entrants later in 2016. Given that EGRX's product can plausibly claim differentiation versus both Treanda (less degradation, possibly a shorter infusion time) and traditional generics (as a liquid versus the lyophilized powder generics), we could still envision EGRX holding on to meaningful volume share in the face of increasing competition over time (we assume a market share of 35% in 2019).
- **Pricing.** During the launch year, we assume EGRX sells its product at an average discount to Treanda's brand price of 60%-65%. In other words, in the period during which EGRX's product has exclusivity, a more modest discount to the brand is to be expected (30% or so is not unreasonable in our view). As competition from traditional generics materializes, pricing obviously starts to erode significantly, and over time, we assume that the discount to the brand will be around 80% in the context of multiple generics on the market.

## Exhibit 12

**BENDAMUSTINE SALES PROJECTIONS (BASE CASE)**

<i>(Sales \$M)</i>	2013A	2014E	2015E	2016E	2017E	2018E	2019E
<b>U.S. Sales</b>							
<b>Total Bendamustine U.S. Sales</b>	<b>\$709</b>	<b>\$766</b>	<b>\$839</b>	<b>\$875</b>	<b>\$905</b>	<b>\$920</b>	<b>\$934</b>
Treanda brand share (Teva)	100%	100%	100%	47%	6%	5%	2%
EP-3101/EP-3102 share (Eagle) <sup>(1)</sup>	0%	0%	0%	40%	45%	40%	35%
aNDA generic share	0%	0%	0%	13%	49%	55%	63%
<i>EP-3101/EP-3102 price discount versus Treanda</i>				63%	80%	83%	83%
<i>Dollar value of bendamustine market after discount</i>				\$328	\$185	\$161	\$160
<b>Eagle bendamustine U.S. Sales</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$131.2</b>	<b>\$83.3</b>	<b>\$64.4</b>	<b>\$56.1</b>

Source: Company reports, and PJC estimates

**DANTROLENE: A NICHE OPPORTUNITY, AND THEN  
POTENTIALLY A TRANSFORMATIVE ONE**

Eagle is developing an optimized formulations of the direct-acting skeletal muscle relaxant dantrolene. Eagle is initially targeting its product for the treatment of malignant hyperthermia, bearing in mind that the original form of dantrolene was approved in MH in 1979. Eagle is also pursuing the development of its formulation in a new therapeutic indication for dantrolene, which is for the emergency treatment of exertional heat stroke, a condition for which there is currently no approved pharmacological treatment.

Eagle's optimized version of dantrolene, known under the proposed trade name of Ryanodex, is a concentrated formulation of the compound (i.e., small volume) that enables for more rapid reconstitution. The product has received orphan drug designation from the FDA for the treatment of MH and EHS. One treatment cycle of Ryanodex, which is presented in a 5 mL vial containing 250 mg of dantrolene in lyophilized powder form, will require only one vial of the product, compared to the 12 vials of the currently available product (known by the trade names of Dantrium and Revonto) that are needed for a given patient. Eagle's product should significantly reduce the preparation time of dantrolene from 15-20 minutes for Dantrium/Revonto to only one minute for its product.

**Dantrolene in Malignant Hyperthermia: A Low-Risk Shot-on-Goal, From Both a  
Regulatory and Commercial Perspective**

Malignant hyperthermia (MH) is a pharmacogenetic disorder of skeletal muscles that can occur as a response to potent volatile anesthetic gases such as halothane, sevoflurane, desflurane and the muscle relaxant succinylcholine, which are administered during a wide variety of surgical procedures. In an episode of MH, muscle metabolism is dramatically increased secondary to an increase in calcium within the muscle, causing the muscles to contract. Symptoms at the onset of a MH episode include a steep rise in body temperature, an increased heart rate, increased carbon dioxide production, muscle rigidity and increased oxygen consumption. If not treated quickly, the symptoms can lead to circulatory collapse and death.

In most cases, the condition is caused by a genetic defect in a calcium channel known as the ryanodine receptor. DNA-based testing suggests that mutations of the ryanodine receptor 1 (RYR1) may lead to a heightened susceptibility to MH episodes, given that the RYR1 receptor is necessary in the calcium release process. Susceptibility to MH is often inherited as an autosomal dominant disorder.

MH is estimated to occur in 1 in 5,000 to 50,000 instances in which patients are given anesthetic gases during surgical procedures. That said, it is believed that MH is most likely more prevalent than these figures suggest, given that many people who are at increased risk of MH are never exposed to the drugs that can trigger a reaction. Eagle estimates that that there are only 500-800 cases of MH in the U.S. each year (in other words, this is a condition that certainly fits into the ultra orphan disease classification).

The agent dantrolene is thought to interfere with muscle contraction, decreasing calcium in muscle cells. It is currently the only accepted pharmaceutical treatment for MH. Dantrolene has also been found to bind to a specific ryanodine protein site. The drug is marketed under the trades name Dantrium and Revonto, with annual sales of around \$20M in the U.S. (ex-U.S. sales are around the same). Despite the drug's effectiveness in treating MH episodes, the lengthy process to preparation Dantrium/Revonto for patient administration is a key



and often life threatening drawback. Both drugs are supplied in 65 mL vials containing 20 mg of dantrolene as lyophilized powders. One treatment cycle of Dantrium/Revonto requires 12 vials of the product for a given patient. These 12 vials each need to be reconstituted to 20 mg/60 mL, for a total of 720 mL of IV fluid. The reconstitution process can take up to 15-20 minutes, bearing in mind this is a life-threatening medical emergency that must be treated immediately.

### Our Thoughts on Market Potential for Dantrolene in MH

Eagle filed its NDA for Ryanodex via 505(b)(2) in January 2014. The company will target the \$20M U.S. market for Dantrium/Revonto within this indication. With a PDUFA for the product likely to be sometime this fall, we are modeling an early 2015 launch of the product. Below we outline our assumptions regarding our base case scenario:

- **Underlying dantrolene market.** We estimate that U.S. sales of Dantrium/Revonto for MH are roughly \$20 million annually. It is estimated that ex-U.S. sales of dantrolene are roughly equivalent to the U.S. market. We note that we do not assume contribution from Ryanodex outside of the U.S. in our model.
- **Pricing.** We assume initial pricing for Ryanodex that is in-line with pricing for one treatment cycle of Dantrium/Revonto (just north of \$1,064, per Wolters Kluwer PriceRx). One treatment cycle of Dantrium/Revonto requires 12 vials, while we assume only one vial per treatment for Ryandox. We model modest annual price increases for Ryanodex post-launch (though given the ultra-orphan nature of this setting, we could easily envision pricing power, particularly once EGRX has captured the lion's share of dantrolene volumes).
- **Market share.** Given the differentiation of Ryanodex versus the predecessor products, we assume that Ryanodex captures nearly half of the dantrolene market by year two post-launch, and 95% of the market by 2021.

#### Exhibit 13

### SALES PROJECTIONS FOR DANTROLENE IN MALIGNANT HYPERTHERMIA

(Sales \$M)	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
<b>Malignant Hyperthermia (MH)</b>									
Total dantrolene U.S. Sales in MH (incl. Dantrium/Revonto & Ryanodex) <sup>(2)</sup>	\$20	\$20	\$20	\$21	\$22	\$24	\$26	\$28	\$29
Total dantrolene treatment cycles in U.S. <sup>(3)</sup>	18,800	18,800	18,800	18,800	18,800	18,800	18,800	18,800	18,800
Brand share (Dantrium/Revonto)	100%	100%	70%	53%	25%	10%	7%	5%	5%
Ryanodex share (Eagle)			30%	47%	75%	90%	93%	95%	95%
aNDA generic share			0%	0%	0%	0%	0%	0%	0%
Total Ryanodex vials sold in U.S. (one vial per treatment cycle)			5,598	8,921	14,100	16,920	17,484	17,860	17,860
Cost per vial of Ryanodex (one treatment course) <sup>(1)</sup>	\$1,064	\$1,064	\$1,064	\$1,143	\$1,229	\$1,321	\$1,421	\$1,495	\$1,570
<b>Dantrolene (Ryanodex) U.S. Sales in Malignant Hyperthermia (MH)</b>			<b>\$6</b>	<b>\$10</b>	<b>\$17</b>	<b>\$22</b>	<b>\$25</b>	<b>\$27</b>	<b>\$28</b>
<b>Total Ryanodex U.S. Sales</b>	<b>\$0</b>	<b>\$0</b>	<b>\$6</b>	<b>\$10</b>	<b>\$66</b>	<b>\$103</b>	<b>\$125</b>	<b>\$138</b>	<b>\$151</b>

(1) We assume initial pricing for 1 vial of Ryanodex is equivalent to the current price of 1 treatment course for Dantrium (~\$1,050) in MH

(2) We assume MH market expansion is driven by pricing power of Ryanodex (given its differentiation versus Dantrium/Revonto); we do not assume growth in volumes in MH

(3) This is an aggregate of Dantrium/Revonto treatment cycles (which require 12 vials per cycle) and Ryanodex treatment cycles (requires only one vial per cycle) in MH

Source: Company reports, PriceRx and PJC estimates

## Dantrolene in Exertional Heat Stroke: A More Conventional Branded Pharmaceutical Product

Eagle's second dantrolene opportunity (known as EP-4104) is being developed to treat exertional heat stroke (EHS), a new indication for which there is no approved pharmacological treatment. We believe the EHS opportunity could be transformational for Eagle, bearing in mind that this is a product that could easily be stocked in ambulances, medical helicopters, hospitals and in other settings such as athletic events.

### Brief Overview of Exertional Heat Stroke

Exertional Heat Stroke (EHS) is as a type of exertional heat illness (EHI), differentiated from and more severe than other heat related illnesses such as exercise-related muscle cramps or exhaustion, heat syncope (i.e., dizziness), and exertional hyponatremia (i.e., when serum-sodium levels fall below key thresholds). EHS can commonly be mistaken for severe forms of exercise or heat exhaustion, which describes a state in which someone becomes unable to continue exercising without significant energy depletion, heavy sweating, sodium loss, and/or potential dehydration. The defining characteristics of EHS include indications of organ failure as a result of hyperthermia and a core body temperature of greater than 104°F (40°C). The condition is likely to occur when one's exertion (and likely a high temperature environment) leads to an overheating of the organ tissues that can cause circulatory failure or a failure of the body's temperature control system in the brain.

Those suffering from EHS are likely to exhibit a variety of symptoms such as sweating, diarrhea, seizures, hyperventilation, hypotension, tachycardia, and coma, among others. The condition can lead to disseminated intravascular coagulation (i.e., over-acting of the proteins that form blood clots), acute renal failure, rhabdomyolysis (i.e., the breakdown and release of muscle fiber content into the bloodstream), and severe lactic acidosis (i.e., buildup of lactic acid in the bloodstream), and has the potential to cause death if not diagnosed and treated quickly. The best way to differentiate this condition from heat exhaustion is to measure rectal temperature and evaluate the patient's cognitive function, which is likely to be severely altered. Given that there are currently no pharmacologic treatments available, the current standard of care for EHS is to physically cool and attempt to hydrate the patient as quickly as possible. This process can be done in various ways, including immersion into a cold body of water or the application of ice packs or cold towels. The use of cold IV fluids may also be used.

The condition is most likely to occur in athletes during the summer or in military personnel training in a high-temperature environment. According to Eagle, EHS may be the leading cause of non-combat related deaths in the armed forces and is one of the top three causes of sudden deaths in athletes. Data compiled by the U.S. military indicates that hospitalizations in the armed forces due to EHS grew from 1.8 per 100,000 to 14.5 per 100,000 from 1980 to 2001 and the overall incidence rate of EHS was 24 per 100,000 by 2008. Additionally, available literature suggests that around 10 per 100,000 participants in marathons suffer from EHS. According to Eagle, anywhere from 23,000-38,000 individuals in the U.S may suffer from EHS in a given year.

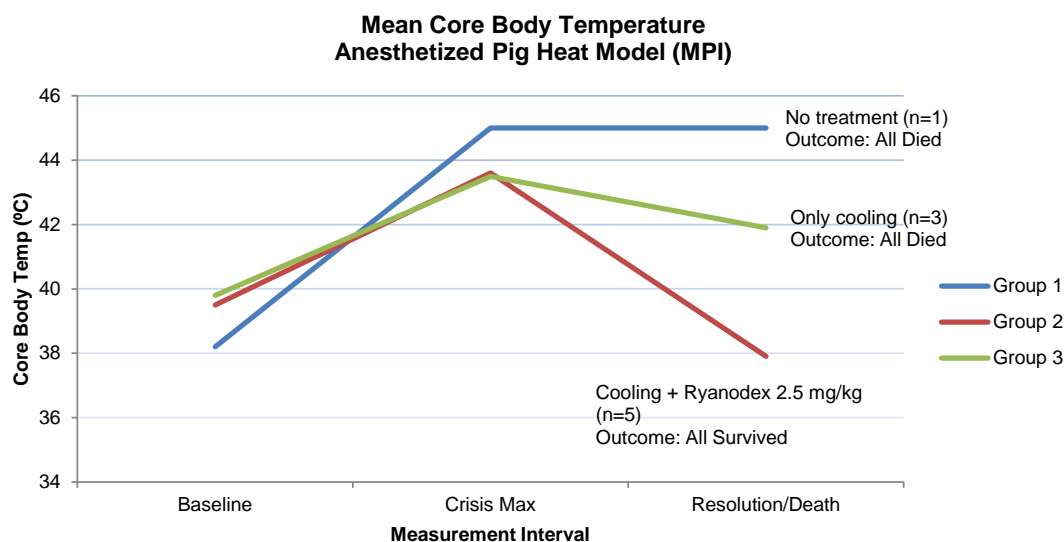
**Connections between malignant hyperthermia and exertional heat stroke.** There are certainly a variety of obvious factors that are likely to increase the risk of EHS during physical exertion such as dehydration, poor physical fitness (also obesity), an inability to properly acclimate to heat, heavy alcohol consumption, and concurrent illness. Other

predisposed medical conditions that magnify the risk of EHS include sickle cell traits, scleroderma, cystic fibrosis, neuroleptic malignant syndrome, and arteriosclerotic vascular disease. Additionally, it is believed that there is a genetic predisposition to EHS that essentially is similar to the genetic predisposition seen in MH cases. Though the particular mechanism that causes EHS episodes is not completely understood, a key component of EHS includes the same defect in the calcium transport in skeletal muscle sarcoplasmic reticulum (i.e., the ability of the muscles to properly contract) or RYR1 mutations that have been associated with MH susceptibility.

**Early studies suggest potential efficacy of dantrolene in EHS.** Eagle conducted a small pilot study designed to evaluate its dantrolene formulation (Ryanodex). A total of 8 MH susceptible pigs were anesthetized and their core temperatures were increased to 41.5 Celsius degrees from 38-39 Celsius degrees at baseline. Each was then assigned to one of three treatment scenarios. One pig was given no treatment, three were provided with the current standard of care for EHS (external cooling and IV hydration), and five were given Ryanodex plus standard of care. Pigs treated with Ryanodex all survived while the pigs that received standard of care or no care whatsoever all died.

Exhibit 14

#### EXERTIONAL HEAT STROKE MODEL ANIMAL PILOT STUDY (N=8)



Source: Company reports and PJC Research

### Phase III Trial for Dantrolene in EHS in the Works

Eagle is aiming to initiate a pivotal study evaluating the safety and efficacy of dantrolene plus standard of care versus standard of care alone (with standard of care being external cooling and IV hydration). This study could very well be conducted in collaboration with the U.S. Military and could begin as early as late 2014. Management has noted that this is likely to be a 50-patient study where subjects are randomized 1:1 to receive dantrolene plus standard of care or standard of care alone. Management has noted that the primary endpoint of the pivotal study will be mostly be determined by the degree of organ damage to patients and/or other biomarkers. In Eagle's early discussions with the FDA, it appears that mortality benefit will not be a primary endpoint measurement. Eagle is also working with the FDA on possible trial sites to conduct the study, which are likely to be military bases in the U.S. or overseas.

### Our Thoughts on Market Potential for Dantrolene in EHS

EGRX's product has received orphan drug designation from the FDA for the treatment of EHS. Eagle anticipates submitting an NDA via the 505(b)(2) pathway for EHS by mid-2016, pointing to the potential for a commercial launch in 2017. Below we outline our assumptions regarding our base case scenario:

- **Total market opportunity for EHS; several distinct channels for use.** We believe there are several distinct channels in which dantrolene for EHS could be utilized. The first is EMS transport, which we divide into ambulances and EMS helicopters. According to Eagle, there are just under 50,000 ambulances and 850 EMS helicopters in the U.S. Another channel is use inside hospitals. We estimate there are roughly 5,800 hospitals in the U.S. with half domiciled in the southern U.S (where EHS episodes are more prevalent given the climate). We would also expect to see significant usage of dantrolene in EHS within the U.S. military and for emergency use during marathons and triathlons.
- **Pricing.** We assume initial pricing for dantrolene in EHS that is in-line with pricing for one treatment cycle of Dantrium/Revonto in MH (just north of \$1,064, per Wolters Kluwer PriceRx).
- **Market share.** Given that there is currently no approved pharmacological treatment for EHS, we expect EGRX's dantrolene product to gain significant traction with all channels listed above.

Exhibit 15

SALES PROJECTIONS FOR DANTROLENE IN EXERTIONAL HEAT STROKE

(Sales \$M)	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
<b>Exertional Heat Stroke (EHS)</b>									
<u>EMS Transport</u>									
Number of ambulances in the U.S.	49,000	49,000	49,000	49,000	49,000	49,000	49,000	49,000	49,000
Number of ambulances stocking dantrolene				0	24,500	39,200	44,100	46,550	48,020
% penetration of U.S. ambulances				0%	50%	80%	90%	95%	98%
New ambulances stocking dantrolene during period (initial stocking)					24,500	14,700	4,900	2,450	1,470
Number of vials stocked per ambulance					1	1	1	1	1
Vials sold to new ambulances					24,500	14,700	4,900	2,450	1,470
Replenish rate of existing ambulances					50%	50%	50%	50%	50%
Number of vials re-stocked on replenish					3	3	3	3	3
Vials sold to existing ambulances (replenish stocking)					0	36,750	58,800	66,150	69,825
<b>Vials Sold to Ambulances</b>					<b>24,500</b>	<b>51,450</b>	<b>63,700</b>	<b>68,600</b>	<b>71,295</b>
Number of EMS helicopters in the U.S.	850	850	850	850	850	850	850	850	850
Number of EMS helicopters stocking dantrolene				0	510	680	765	808	833
% penetration of U.S. EMS helicopters				0%	60%	80%	90%	95%	98%
New EMS helicopters stocking dantrolene during period					510	170	85	43	26
Number of vials stocked per EMS helicopter					1	1	1	1	1
Vials sold to new EMS helicopters					510	170	85	43	26
Replenish rate of existing EMS helicopters					50%	50%	50%	50%	50%
Number of vials re-stocked on replenish					2	2	2	2	2
Vials sold to existing EMS helicopters (replenish stocking)					0	510	680	765	808
<b>Vials Sold to EMS Helicopters</b>					<b>510</b>	<b>680</b>	<b>765</b>	<b>808</b>	<b>833</b>
<u>Hospitals</u>									
Number of hospitals in the U.S.	5,800	5,800	5,800	5,800	5,800	5,800	5,800	5,800	5,800
Number of hospitals in southern U.S. states	2,900	2,900	2,900	2,900	2,900	2,900	2,900	2,900	2,900
Total number of southern hospitals stocking dantrolene				0	1,740	2,320	2,755	2,813	2,871
% penetration of U.S. Southern hospitals				0%	60%	80%	95%	97%	99%
New Southern hospitals stocking dantrolene during period (initial stocking)					1,740	580	435	58	58
Number of vials stocked per hospital					4	4	4	4	4
Vials sold to new Southern hospitals (initial stocking)					6,960	2,320	1,740	232	232
Replenish rate of existing southern hospitals					40%	40%	40%	40%	40%
Number of vials re-stocked on replenish					4	4	4	4	4
Vials sold to existing southern hospitals (replenish stocking)					0	2,784	3,712	4,408	4,501
<b>Vials Sold to Southern Hospitals</b>					<b>6,960</b>	<b>5,104</b>	<b>5,452</b>	<b>4,640</b>	<b>4,733</b>
Number of hospitals in Northern U.S. states	2,900	2,900	2,900	2,900	2,900	2,900	2,900	2,900	2,900
Total number of northern hospitals stocking dantrolene				0	1,450	2,175	2,610	2,755	2,842
% penetration of U.S. northern hospitals				0%	50%	75%	90%	95%	98%
New Northern hospitals stocking dantrolene during period (initial stocking)					1,450	725	435	145	87
Number of vials stocked per hospital					4	4	4	4	4
Vials sold to new Northern hospitals (initial stocking)					5,800	2,900	1,740	580	348
Replenish rate of existing Northern hospitals					20%	20%	20%	20%	20%
Number of vials re-stocked on replenish					4	4	4	4	4
Vials sold to existing Northern hospitals (replenish stocking)					0	1,160	1,740	2,088	2,204
<b>Vials Sold to Northern Hospitals</b>					<b>5,800</b>	<b>4,060</b>	<b>3,480</b>	<b>2,668</b>	<b>2,552</b>
Active U.S. military personnel	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000
<b>Total # of vials sold to U.S. Military</b>					<b>6,150</b>	<b>8,871</b>	<b>9,519</b>	<b>10,471</b>	<b>11,518</b>
Marathons/Triathlons in the U.S.	375	375	375	375	375	375	375	375	375
<b>Total # of vials stocked by Marathons/Triathlons</b>					<b>2,000</b>	<b>3,350</b>	<b>3,853</b>	<b>4,430</b>	<b>5,095</b>
Total Number of vials sold in EHS					45,920	73,515	86,768	91,617	96,026
Cost per vial					\$1,050	\$1,103	\$1,158	\$1,216	\$1,276
<b>Dantrolene U.S. Sales in Exertional Heat Stroke (EHS)</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$48</b>	<b>\$81</b>	<b>\$100</b>	<b>\$111</b>	<b>\$123</b>

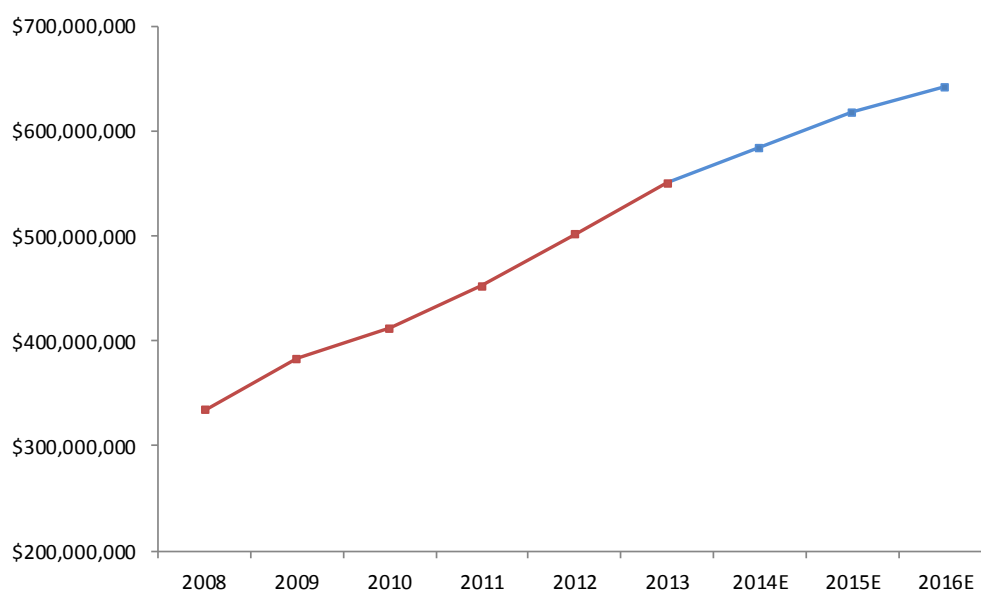
Source: Company reports, Industry reports, and PJC estimates

## BIVALIRUDIN: OPTIONALITY ON A SIZABLE SHOT-ON-GOAL

Bivalirudin is an anticoagulant marketed under the trade name Angiomax by the The Medicines Company (MDCO). The brand is a lyophilized powder (250 mg/vial) that needs to be reconstituted prior to use with 5 mL of sterile water for injection and further diluted in 50 mL of 5% dextrose injection or 0.9% sodium chloride injection to yield a final bivalirudin concentration of 5 mg/mL. The drug has managed to establish a fairly strong presence in the highly crowded anti-coagulation treatment landscape, with U.S. sales of Angiomax reaching \$550 million in 2013, up 10% over 2012. We estimate that U.S. sales will be close to \$585 million in 2014.

Exhibit 16

### ANGIOMAX U.S. BRAND SALES



Source: Company reports and PJC estimates  
Note: Sales estimates for 2014 and 2015 are PJC derived

Eagle's improved formulation (known as EP-6101) is ready-to-use without reconstitution for IV infusion without dilution. Eagle anticipates submitting an NDA filing for EP-6101 by 1H15. Management expects that it could launch its product in the 2017 timeframe, ahead of potential traditional generic launches in 2019 (MDCO has settlements in place with two Angiomax generic filers, but patent litigation with other filers is still ongoing; more on this below).

## Overview of Patents on Angiomax

There are three patents on Angiomax that are listed in the FDA's Orange Book. We provide a brief overview below:

- Patent #5,196,404 (or the '404 patent). This is the primary composition of matter of patent. The expiry is in June 2015 (this includes an additional six months of pediatric exclusivity).
- Patents #7,582,727 (the '727 patent) and #7,598,343 (the '343 patent). This covers a more consistent and improved Angiomax drug product and its manufacturing processes. The patent asserts that certain impurities may be generated during the synthesis of the compound. The claims speak to methods of minimizing certain impurities, specifically around ways to reduce the presence of a *"major degradation product, i.e., Asp.sup.9-bivalirudin, which may contribute to improved stability and shelf-life."* These patents expire in January 2029 (also inclusive of six months of pediatric exclusivity).

**Two MDCO settlements with generic filers currently in place; decision in Hospira case looming, as well as a trial versus Mylan in 2H14.** We currently know of six generics companies that have pending aNDA filings on Angiomax. Given that none of the aNDA filers are challenging the '404 or composition of matter patent, we see June 2015 as the earliest likely launch date for an FDA-approved aNDA generic for Angiomax. MDCO reached a settlement with Teva in October of 2011, which allows for the launch of its generic on 6/30/19 and MDCO also reached a settlement with APP Pharma, which allows for the launch of its generic on 5/1/19.

The remaining aNDA filers have 30 month stay expiries as late as April 2014. Though Teva and APP were the earliest aNDA filers, they would in theory be in a position to have 180 days of exclusivity (possibly shared exclusivity if they were indeed both first). However, it has been well beyond 30 months since these filings were submitted and the FDA has not granted tentative approvals. The only tentative approval that has been granted to date has been on Hospira's filing (Mylan, Dr. Reddy's and Sun also have pending filings). Hatch-Waxman dictates that a generics company that has first-to-file status that has entered into a settlement for a date-certain launch longer-term does not forfeit its right to exclusivity if it were to receive an approval within 30 months of its submission. That exclusivity may be forfeited if there is no approval within that timeframe. The absence of a tentative approval for Teva and APP points to no right to exclusivity. In this context, other filers are pushing ahead with their litigation, given the real potential that a legal victory could point to a generic launch with exclusivity (or at a minimum in an uncrowded market). MDCO is expecting that a trial with aNDA filer Mylan will take place in June 2014 (recall that the markman hearing outcome in this case appeared to be more favorable to MDCO versus the outcome in the Markman hearing in the Hospira case). We would expect to see a district court decision in the Hospira case by mid-2014 (recall the trial was held in September 2013). To our knowledge, trials have not been scheduled in the cases of the other two pending aNDA filings from Sun and Dr. Reddy's.

**Legal outcomes very much up in the air; settlements still a very real possibility.** In July 2013, the Federal District Court for Delaware issued its ruling on claims construction in MDCO's patent litigation versus Hospira regarding its generic version of Angiomax (the Markman hearing was held on 12/5/12). The outcome did not appear to be favorable to MDCO, though we'd note that in two separate Angiomax cases (Mylan and Dr. Reddy's/Sun Pharma), claims construction was favorable to MDCO. Given the discordant outcomes

thus far and the reality that the last Orange Book patents expire in January 2029, we believe that settlements with the remaining filers (i.e., Hospira) allowing for launches not long before Teva and APP launch in mid-2019 (per previous settlements) are still a realistic possibility.

With EGRX filing on its product by 1H15, EGRX would be in a position to launch sometime in 2H17 following the expiry of its 30-month stay. EGRX is the only 505(b)(2) filer, and management has noted that its formulation is distinctly different from that of the innovator (and its associated manufacturing process) and therefore does not infringe on the MDCO patents. As such, it is theoretically possible that EGRX wins in its case, paving the way for a 2H17 launch, while the aNDA filers lose their cases or settle for MDCO for a launch at a date closer to the Teva/APP launches in 2019. That said, out of an abundance of conservatism, we do not include revenue contribution from EGRX's bivalirudin product in our model.

## Exhibit 17

**OVERVIEW OF ANGIOMAX ANDA FILERS**

Filer	Date Filed	Patents challenged	30-month stay expiry	Details on litigation/settlement
Teva	September 2009	'727	expired	Launch of Teva's generic on 6/30/19
APP	September 2009	'727	expired	Launch of APP's generic on 5/1/2019
Hospira	July 2010	'727, '343	expired	Trial held in September 2013; district court decision expected by mid-2014
Mylan	January 2011	'727, '343	expired	Trial scheduled for July 2014
Dr. Reddy's	March 2011	'727, '343	expired	No trial date set
Sun	October 2011	'727, '343	April 2014	No trial date set
Apotex	March 2013	'727, '343	November 2015	In discovery process; No trial date set

Source: Company reports



## OTHER TOP-LINE DRIVERS

### Argatroban Royalties: A Modest Contributor

Argatroban is an IV-available direct thrombin inhibitor. The drug is approved for the treatment of heparin-induced thrombocytopenia (HIT) and in patients with or at risk of HIT undergoing percutaneous coronary intervention (PCI). The drug is currently sold in 250 mL vials by GlaxoSmithKline (who markets the brand) and West-ward (Hikma Pharmaceuticals), 125 mL vials by Sandoz (Novartis), and 50 mL vials by both Eagle/The Medicines Company and Sandoz. Per IMS Health, the various argatroban products had annual sales of \$79 million in the U.S in 2013, a decline of 25% from 2012.

Eagle's formulation (EP-1101) was approved by the FDA in June 2011 and is currently marketed by The Medicines Company (MDCO) through a licensing agreement that provides MDCO with the exclusive rights to market the drug in the U.S. and Canada (along with the right to be the first negotiator in potential commercializations in other countries, except China). The companies entered into this agreement with MDCO in September 2009, with Eagle receiving an upfront payment of \$5 million in addition to future royalties on net sales (the companies split gross profits 50/50). Eagle also has a licensing agreement with Sandoz, which distributes a generic version of argatroban supplied by Eagle in 50 mg/50 mL vials. Sandoz also markets 125 mg/125 mL vials of argatroban and, via the licensing agreement, pays Eagle a majority of the net profits received from the drug. Per IMS Health, argatroban products marketed by MDCO and Sandoz held 26% share of the total market in 2013. MDCO reported 2013 sales of argatroban of \$11.3 million, up 55% from 2012, though MDCO was off the market from December 2011 to April 2012 following a voluntary recall from Eagle due to the presence of particulate matter in some vials of the product. Though West-Ward was able to launch its generic version in early 2013 following a U.S. District Court ruling, a separate court case precluded aNDA filer Teva from launching a generic version until late June 2014. Eagle recorded argatroban royalties totaling \$2.5 million in 2012 as a result of its agreements with MDCO and Sandoz.

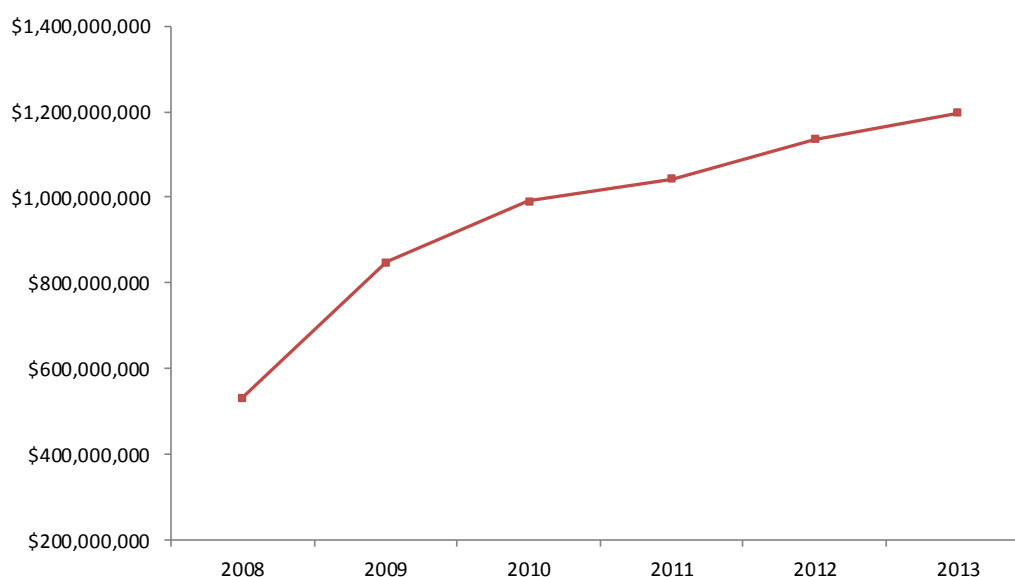
The branded form of argatroban is currently supplied in a 2.5 mL vial with 100 mg/mL of active pharmaceutical ingredient (API). This form requires the use of a 250 mL intravenous (IV) bag in order to achieve a 100-fold dilution necessary for infusion, which can result in approximately 30% waste due to the prophylactic administration that occurs as doctors await the HIT test results of the patient. Additionally, the IV bag must be changed every 24 hours to prevent infection. Conversely, EP-1101 is supplied in a ready to use, single-use vial that contains 50 mg of drug in a 50 mL aqueous solution that can be easily attached to an IV pole via a ring sling. Eagle estimates that the use EP-1101 results in a mere 1% of wasted drug in addition to the efficiency advantages provided by its formulation.

## Pemetrexed: Sizable Market but Competition Likely To Be Stiff

Pemetrexed is an IV-administered oncology product that was approved in February 2004 for the treatment of mesothelioma and later for the locally advanced or metastatic non-small cell lung cancer (NSCLC). The drug is currently marketed under the trade name Alimta by Eli Lilly (LLY). The chemotherapy drug is part of the folate antimetabolite class and works by inhibiting three enzymes that synthesize purine and pyrimidine, which are necessary for formation of the DNA and RNA that are in turn necessary for growth and stability of the cancer cells in question. In 2013, LLY reported worldwide sales of \$2.7 billion (approximately 45% in U.S. sales), an increase of 4% over 2012. Per IMS, 2013 sales totaled \$1.2 billion.

Exhibit 18

### ALIMTA BRAND SALES



Source: Company reports and PJC estimates  
Note: Sales estimates are consensus estimates

**Lilly's ongoing patent challenges should yield news in 1H14.** There are two Orange Book listed patents protecting Alimta, with expiries of January 2017 and May 2022 (including six months of pediatric exclusivity). There are at least six aNDA filers seeking approval to launch generic versions of Alimta, including Teva, APP, Barr, Pliva, Accord, and Apotex. LLY is currently awaiting the result of an August 2013 case against four filers (who are challenging the company's '209 patent that expires in 2022). We should see a decision in 1H14, but any decision is likely to result in an appeals process. Patents on Alimta are also currently being challenged in the European Patent Office (where an initial judgment in LLY's favor was appealed) in addition to ongoing proceedings in Germany and the UK, where trials are expected around March and April of 2014, respectively.

**Eagle formulation provides various benefits versus the brand.** Alimta, like Angiomax, is a lyophilized powder that needs to be reconstituted prior to use with sodium chloride for IV infusion and used within 24 hours given some product stability concerns. The need for reconstitution creates certain limitations around the products' use in addition to the time

necessary to complete this process, which can also add to the amount of time that a patient must spend in an infusion clinic (and limit the amount of patients that may be treated in a given day). This reconstitution process can also lead to potential dosing errors and also releases cytotoxic vapors that can be harmful to those responsible for administration. Eagle's product (known as EP-5101) is ready-to-use without reconstitution for IV infusion without dilution and also includes extended stability characteristics, which are likely to improve efficiency in the clinic while eliminating some of the safety concerns mentioned above. The company believes its product is positioned to launch concurrently with the first FDA-approved Alimta generics. Eagle expects to file an NDA on EP-5101 by 4Q15.

## COMPANY MANAGEMENT

**Scott Tarriff, Founder, President, and Chief Executive Officer.** Mr. Tarriff founded Eagle Pharmaceuticals in January 2007 and has served as President and CEO since the company's inception. Prior to founding Eagle, he was President and CEO of Par Pharmaceuticals from September 2004 to September 2006 after joining Par in 1998. Before joining Par, Mr. Tarriff held various positions at Bristol-Myers Squibb including senior director of marketing. He holds a B.S. in marketing from Penn State University and an MBA from Rider College.

**Ken Degen, Senior Vice President of Sales & Marketing.** Mr. Degen has served as SVP of Sales & Marketing at Eagle since January 2009. Prior to joining Eagle, he held various management positions focused on sales and marketing over a 20-year period at Schering-Plough Pharmaceuticals. Mr. Degen holds a B.S. in business administration from George Mason University.

**Peter Grebow, PhD, Executive Vice President of Research & Development.** Dr. Grebow has served as EVP of R&D since October 2013. Prior to joining Eagle, he held several senior management positions over 20 years at Cephalon (now part of Teva). Dr. Grebow holds an A.B. degree in chemistry from Cornell University, an M.S. in chemistry from Rutgers University and a PhD in physical biochemistry from the University of California, Santa Barbara.

**David E. Riggs, Chief Financial Officer.** Mr. Riggs has served as CFO of Eagle since November 2013. Prior to Eagle, he served as a healthcare consultant at a number of biotechnology companies. From March 2006 to May 2010, he served as CFO of Ferring Pharmaceuticals. His earlier experience includes various positions (including CEO) at eXegenics (now OPKO Health), Axys Pharmaceuticals, Unimed Pharmaceuticals, and Fujisawa Pharmaceuticals. Mr. Riggs holds a B.S. in accounting from the University of Illinois and an MBA from DePaul University.

**Paul Bruinenberg, M.D., Chief Medical Officer and Head of Research & Development.** Dr. Bruinenberg has served as CMO and head of R&D at Eagle since November 2011. Prior to joining Eagle, he served as senior medical director of Aradigm Corporation, following a one year stint as VP of clinical research at Fulcrum Pharma from May 2006 to May 2007. Dr. Bruinenberg's earlier experience includes holding various positions at Yamanouchi Pharmaceuticals (now part of Astellas) and Roche, in addition to founding his own clinical research consulting practice. He holds a medical degree from the University of Stellenbosch and MBAs from the University of Nijmegen and Rochester University.

**Steven L. Krill, PhD, Chief Scientific Officer.** Dr. Kill has served as CSO at Eagle since February 2013, having served as VP of Pharmaceutical Development from October 2011 to February 2013. Prior to joining Eagle, he served as VP of Scientific Affairs at Teva Parenteral Medicines from March 2009 to August 2011. His earlier experience includes various positions at Boehringer Ingelheim, Lipocine, Novartis and Abbott Labs. Dr. Krill holds a B.S. in pharmacy and an M.S. in pharmaceutical sciences from the University of Cincinnati and a PhD in pharmaceuticals from the University of Utah.

## INVESTMENT RISKS

**FDA and clinical trial risk.** Eagle's regulatory risks are generally similar to those of its other specialty pharma peers. Its generic products, like bendamustine, have minimal approval risk. However, dantrolene is a brand opportunity. Since the old version of dantrolene is already approved for malignant hyperthermia (MH), approval risk in this setting should be limited. That said, exertional heat stroke (EHS) would be a new use of the product, and Eagle is running a Phase III study in this setting. As such, there is always the possibility that the trial fails, though we would keep in mind that MH and EHS are essentially similar conditions, which potentially mitigates the clinical risk in the EHS setting.

**Legal risks.** Though Eagle's generics are not traditional, vanilla generics, the companies that distribute the predecessor, innovator products will nonetheless claim that Eagle infringes on their intellectual property and will pursue litigation. This is already the case in the matter of bendamustine, and will likely be the case for most, if not all, of Eagle's other generic filings. As such, there is the risk that the courts will determine that Eagle infringes on patents protecting the innovator products, preventing Eagle from launching its generics. That said, we would keep in mind that Eagle's formulations of these generics are different (in other words, it is the same underlying molecule but a different, typically optimized, way of delivering said molecule). Further, many of the generics that Eagle is pursuing are protected by relatively thin and narrow patents (such as patents on the formulations of the innovator products; this is bearing in mind that Eagle is developing different formulations). As such, Eagle is positioning itself so that it does not infringe on innovator patents. That said, brand companies are sophisticated, and there is always the risk that they will succeed in their litigation.

**Competition, both from brands and generics.** Eagle is aiming to bring its generics to market ahead of other generic companies that are making conventional copies of brand products. The timing of additional competition on products like bendamustine is uncertain, and if Eagle does not succeed in its litigation, it may be entering markets along with several other generic competitors (meaning pricing pressure and more limited margins).

# Eagle Pharmaceuticals - Quarterly and Annual Income Statement

Fiscal Year Ends December 31

(\$ In millions, except for EPS)

	2014E					2015E									
	2013A	1QE	2QE	3QE	4QE	2014E	1QE	2QE	3QE	4QE	2015E	2016E	2017E	2018E	2019E
<b>Revenues</b>															
Bendamustine 505(b)(2) generic sales											\$0.0	\$131.2	\$83.3	\$64.4	\$56.1
Ryanodex (dantrolene) - exertional heat stroke (EHS)											\$0.0	\$0.0	\$48.2	\$81.1	\$100.4
Ryanodex (dantrolene) - malignant hyperthermia (MH)							\$1.0	\$1.3	\$1.7	\$2.0	\$6.0	\$10.2	\$17.3	\$22.4	\$24.8
Ryanodex (dantrolene) franchise sales							\$1.0	\$1.3	\$1.7	\$2.0	\$6.0	\$10.2	\$65.5	\$103.4	\$125.3
Bivalirudin 505(b)(2) generic sales															
Pemetrexed 505(b)(2) generic sales															
Argatroban royalties	\$17.7	\$2.0	\$1.8	\$1.5	\$1.3	\$6.5	\$1.0	\$0.8	\$0.6	\$0.6	\$3.0	\$2.5	\$2.0	\$2.0	\$2.0
Other revenues	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total revenue</b>	<b>\$17.7</b>	<b>\$2.0</b>	<b>\$1.8</b>	<b>\$1.5</b>	<b>\$1.3</b>	<b>\$6.5</b>	<b>\$2.0</b>	<b>\$2.0</b>	<b>\$2.3</b>	<b>\$2.6</b>	<b>\$9.0</b>	<b>\$143.9</b>	<b>\$150.8</b>	<b>\$169.8</b>	<b>\$183.3</b>
Cost of sales	11.8	1.0	0.9	0.8	0.6	3.3	0.8	0.7	0.7	0.8	3.0	49.7	46.5	52.6	54.7
<b>Gross Profit</b>	<b>\$5.9</b>	<b>\$1.0</b>	<b>\$0.9</b>	<b>\$0.8</b>	<b>\$0.6</b>	<b>\$3.3</b>	<b>\$1.3</b>	<b>\$1.3</b>	<b>\$1.6</b>	<b>\$1.8</b>	<b>\$6.0</b>	<b>\$94.2</b>	<b>\$104.3</b>	<b>\$117.2</b>	<b>\$128.6</b>
Research & development	10.2	3.6	3.5	3.7	3.8	14.6	3.9	4.0	4.0	4.1	16.0	16.5	17.0	17.5	17.5
Selling, general, and administrative	4.4	1.7	2.0	2.2	3.0	8.9	3.4	4.0	4.5	5.3	17.2	20.0	25.0	32.0	37.5
<b>Total expenses <sup>(1)</sup></b>	<b>\$26.3</b>	<b>\$6.3</b>	<b>\$6.4</b>	<b>\$6.7</b>	<b>\$7.4</b>	<b>\$26.8</b>	<b>\$8.1</b>	<b>\$8.7</b>	<b>\$9.2</b>	<b>\$10.2</b>	<b>\$36.2</b>	<b>\$86.2</b>	<b>\$88.5</b>	<b>\$102.1</b>	<b>\$109.7</b>
<b>Operating Income</b>	<b>(\$8.6)</b>	<b>(\$4.3)</b>	<b>(\$4.6)</b>	<b>(\$5.2)</b>	<b>(\$6.2)</b>	<b>(\$20.3)</b>	<b>(\$6.1)</b>	<b>(\$6.7)</b>	<b>(\$6.9)</b>	<b>(\$7.6)</b>	<b>(\$27.2)</b>	<b>\$57.7</b>	<b>\$62.3</b>	<b>\$67.7</b>	<b>\$73.6</b>
Other income (expense), net	1.8	(0.2)	(0.2)	(0.2)	(0.2)	(0.6)	(0.2)	(0.2)	(0.2)	(0.2)	(0.6)	0.0	0.2	0.2	0.2
<b>Income (loss) before taxes</b>	<b>(\$6.8)</b>	<b>(\$4.5)</b>	<b>(\$4.8)</b>	<b>(\$5.3)</b>	<b>(\$6.3)</b>	<b>(\$20.9)</b>	<b>(\$6.2)</b>	<b>(\$6.8)</b>	<b>(\$7.1)</b>	<b>(\$7.7)</b>	<b>(\$27.8)</b>	<b>\$57.7</b>	<b>\$62.5</b>	<b>\$67.9</b>	<b>\$73.8</b>
Income tax provision	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(3.1)	(13.6)	(22.1)
<b>non-GAAP Net income (loss)</b>	<b>(\$6.8)</b>	<b>(\$4.5)</b>	<b>(\$4.8)</b>	<b>(\$5.3)</b>	<b>(\$6.3)</b>	<b>(\$20.9)</b>	<b>(\$6.2)</b>	<b>(\$6.8)</b>	<b>(\$7.1)</b>	<b>(\$7.7)</b>	<b>(\$27.8)</b>	<b>\$57.7</b>	<b>\$59.4</b>	<b>\$54.3</b>	<b>\$51.7</b>
<b>non-GAAP EPS, basic</b>	<b>(\$0.65)</b>	<b>(\$0.36)</b>	<b>(\$0.34)</b>	<b>(\$0.38)</b>	<b>(\$0.44)</b>	<b>(\$1.53)</b>	<b>(\$0.43)</b>	<b>(\$0.46)</b>	<b>(\$0.47)</b>	<b>(\$0.47)</b>	<b>(\$1.84)</b>	<b>\$3.36</b>	<b>\$3.31</b>	<b>\$2.91</b>	<b>\$2.66</b>
<b>non-GAAP EPS, diluted</b>	<b>(\$0.65)</b>	<b>(\$0.36)</b>	<b>(\$0.34)</b>	<b>(\$0.38)</b>	<b>(\$0.44)</b>	<b>(\$1.53)</b>	<b>(\$0.43)</b>	<b>(\$0.46)</b>	<b>(\$0.47)</b>	<b>(\$0.47)</b>	<b>(\$1.84)</b>	<b>\$2.49</b>	<b>\$2.48</b>	<b>\$2.20</b>	<b>\$2.03</b>
Shares outstanding, basic <sup>(2)</sup>	10.5	12.2	13.9	14.1	14.3	13.6	14.5	14.7	14.9	16.4	15.1	17.2	17.9	18.7	19.4
Shares outstanding, diluted <sup>(2)</sup>	10.5	12.2	13.9	14.1	14.3	13.6	14.5	14.7	14.9	16.4	15.1	23.2	23.9	24.7	25.4
<b>Expenses as % of sales:</b>															
COGS	66.7%	50.0%	50.0%	50.0%	50.0%	50.0%	37.5%	34.4%	31.7%	30.9%	33.4%	34.6%	30.9%	31.0%	29.9%
R&D												11.5%	11.3%	10.3%	9.5%
SG&A												13.9%	16.6%	18.8%	20.5%
<b>Margins:</b>															
Gross margin	33.3%	50.0%	50.0%	50.0%	50.0%	50.0%	62.5%	65.6%	68.3%	69.1%	66.6%	65.4%	69.1%	69.0%	70.1%
Operating margin												40.1%	41.3%	39.9%	40.1%
Net income												40.1%	39.4%	32.0%	28.2%
Income Tax												0.0%	5.0%	20.0%	30.0%
<b>Y-O-Y Growth rates:</b>															
<b>Total revenue</b>											<b>37.8%</b>	<b>1507.1%</b>	<b>4.8%</b>	<b>12.6%</b>	<b>8.0%</b>
R&D											9.6%	3.1%	3.0%	2.9%	0.0%
Selling, general, and administrative											93.3%	16.3%	25.0%	28.0%	17.2%
Operating profit														8.6%	8.7%
Net income														-8.5%	-4.9%
<b>EPS</b>															

(1) Total expenses include COGS

(2) Reflects a modest equity capital raise in 2015

Proprietary to Piper Jaffray & Co. March 6, 2014

Eagle: David Amsellem 212.284.9455

Current disclosure information for this company can be found at

<http://www.piperjaffray.com/researchdisclosures>

# Eagle Pharmaceuticals - Annual Cash Flow Statement

(\$ in millions)

	2012A	2013E	2014E	2015E	2016E	2017E	2018E
<b>Beginning Cash &amp; Equivalents</b>	<b>\$8.1</b>	<b>\$10.5</b>	<b>\$10.0</b>	<b>\$43.6</b>	<b>\$32.0</b>	<b>\$96.4</b>	<b>\$161.9</b>
<b>Operating Activities</b>							
Net Income (Loss)	(\$2.5)	(\$3.3)	(\$20.9)	(\$27.8)	\$57.7	\$59.4	\$54.3
Depreciation & Amortization	\$0.1	\$0.0	\$1.0	\$1.0	\$1.0	\$1.0	\$1.0
Other	\$0.5	\$0.2	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Stock-based Compensation	\$0.1	\$0.1	\$2.0	\$2.0	\$2.0	\$2.0	\$2.0
Net Change in Assets and Liabilities	\$0.0	\$3.0	\$5.7	(\$10.7)	(\$0.4)	(\$0.9)	\$0.0
<b>Cash From Operations</b>	<b>(\$1.8)</b>	<b>\$0.0</b>	<b>(\$12.2)</b>	<b>(\$35.5)</b>	<b>\$60.3</b>	<b>\$61.5</b>	<b>\$57.3</b>
<b>Investing Activities</b>							
Capital Expenditures	\$0.0	(\$0.0)	(\$1.0)	(\$1.0)	(\$1.0)	(\$1.0)	(\$1.0)
Short-Term Investments	\$1.5	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Acquisition of Tangible Assets	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Acquisition of Intangibles	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Other Investment	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Cash From Investing Activities</b>	<b>\$1.5</b>	<b>(\$0.0)</b>	<b>(\$1.0)</b>	<b>(\$1.0)</b>	<b>(\$1.0)</b>	<b>(\$1.0)</b>	<b>(\$1.0)</b>
<b>Financing Activities</b>							
Debt Issuance	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Debt Repayments	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Dividends	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Share Repurchases	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Stock and Option Issuances	\$0.0	\$0.0	\$50.3	\$25.0	\$5.0	\$5.0	\$5.0
Other, Net	\$0.0	(\$0.5)	(\$3.5)	\$0.0	\$0.0	\$0.0	\$0.0
<b>Cash From Financing Activities</b>	<b>\$0.0</b>	<b>(\$0.5)</b>	<b>\$46.7</b>	<b>\$25.0</b>	<b>\$5.0</b>	<b>\$5.0</b>	<b>\$5.0</b>
Currency Translation Differences	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Net Change In Cash	(\$0.3)	(\$0.5)	\$33.6	(\$11.5)	\$64.3	\$65.5	\$61.3
<b>Year End Cash &amp; Equivalents</b>	<b>\$7.8</b>	<b>\$10.0</b>	<b>\$43.6</b>	<b>\$32.0</b>	<b>\$96.4</b>	<b>\$161.9</b>	<b>\$223.2</b>

Proprietary to Piper Jaffray & Co. March 6, 2014

Eagle: David Amsellem 212.284.9455

# Eagle Pharmaceuticals - Annual Balance Sheet

(\$ in millions)

	2012A	2013E	2014E	2015E	2016E	2017E	2018E
<b>Current Assets</b>							
Cash & Equivalents	\$5.1	\$10.0	\$43.6	\$32.0	\$96.4	\$161.9	\$223.2
Marketable Securities	\$1.5	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Accounts Receivable, net	\$1.6	\$6.6	\$0.6	\$7.9	\$8.3	\$9.3	\$10.0
Inventories	\$0.1	\$0.0	\$1.1	\$5.4	\$6.4	\$7.2	\$7.5
Other Current Assets	\$0.6	\$0.4	\$0.4	\$0.5	\$0.6	\$0.6	\$0.7
<b>Total Current Assets</b>	<b>\$8.9</b>	<b>\$16.9</b>	<b>\$45.7</b>	<b>\$45.9</b>	<b>\$111.6</b>	<b>\$179.0</b>	<b>\$241.5</b>
Property, Plant & Equipment, Net	\$0.5	\$0.4	\$0.4	\$0.4	\$0.4	\$0.4	\$0.4
Restricted Cash	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Other Assets	\$0.1	\$0.7	\$0.7	\$0.7	\$0.7	\$0.7	\$0.7
<b>Total Assets</b>	<b>\$9.4</b>	<b>\$18.0</b>	<b>\$46.8</b>	<b>\$46.9</b>	<b>\$112.6</b>	<b>\$180.1</b>	<b>\$242.5</b>
<b>Liabilities &amp; Equity</b>							
Current Liabilities	\$20.9	\$17.2	\$18.1	\$19.0	\$20.0	\$20.9	\$22.0
Total Debt	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Other Liabilities	\$82.0	\$0.0	(\$3.5)	(\$3.5)	(\$3.5)	(\$3.5)	(\$3.5)
Equity	(\$93.4)	\$0.8	\$32.2	\$31.4	\$96.2	\$162.6	\$224.0
<b>Total Liabilities &amp; Equity</b>	<b>\$9.4</b>	<b>\$18.0</b>	<b>\$46.8</b>	<b>\$46.9</b>	<b>\$112.6</b>	<b>\$180.1</b>	<b>\$242.5</b>

Proprietary to Piper Jaffray & Co. March 6, 2014

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Notes: The boxes on the Rating and Price Target History chart above indicate the date of the Research Note, the rating, and the price target. Each box represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first Note written during the past three years.

## Legend:

I: Initiating Coverage  
R: Resuming Coverage  
T: Transferring Coverage  
D: Discontinuing Coverage  
S: Suspending Coverage  
OW: Overweight  
N: Neutral  
UW: Underweight  
NA: Not Available  
UR: Under Review

Distribution of Ratings/IB Services Piper Jaffray				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OW]	353	59.53	82	23.23
HOLD [N]	220	37.10	22	10.00
SELL [UW]	20	3.37	0	0.00

Note: Distribution of Ratings/IB Services shows the number of companies currently in each rating category from which Piper Jaffray and its affiliates received compensation for investment banking services within the past 12 months. FINRA rules require disclosure of which ratings most closely correspond with "buy," "hold," and "sell" recommendations. Piper Jaffray ratings are not the equivalent of buy, hold or sell, but instead represent recommended relative weightings. Nevertheless, Overweight corresponds most closely with buy, Neutral with hold and Underweight with sell. See Stock Rating definitions below.

**Analyst Certification — David Amsellem, Sr. Research Analyst**

— Traver A. Davis, Research Analyst

— Michael H. Lehrhoff, Research Analyst

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