EDISON

PDL BioPharma

Financial update

Investing in Evofem

Pharma & biotech

PDL announced that it will invest a total of up to $60m in two tranches of $30m each in Evofem, a women's health company that is preparing to submit an NDA for Amphora, a non-hormonal female contraceptive, in H219 with a launch expected in 2020. In December, Evofem announced that it achieved the primary endpoint in the 1,400-patient AMPOWER trial with a seven-cycle cumulative pregnancy probability of 14% with the upper limit of the confidence interval at 18%. The pre-specified hurdle in the trial, as agreed to by the FDA, was a seven-cycle pregnancy rate of 16.5% with an upper limit of the confidence interval at 21%.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/17	320.1	200.3	0.81	0.00	4.7	N/A
12/18	198.1	78.8	0.45	0.00	8.5	N/A
12/19e	122.5	58.7	0.38	0.00	10.0	N/A
12/20e	124.5	59.8	0.37	0.00	10.3	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

A non-hormonal method of contraception

Amphora is a mix of L-lactic acid, citric acid and potassium bitartrate, all compounds that are considered to be generally regarded as safe (GRAS) by the FDA. Amphora works by maintaining the vaginal pH level in the 3.5–4.5 range, which is mildly acidic and inhospitable to sperm, which requires a more neutral pH environment (semen is alkaline with a pH over 7). Acidity is also not ideal for certain viral and bacterial pathogens.

Targeting an extremely large market

According to the Centers for Disease Control and Prevention (CDC), 61.7% of the 60.9 million women aged 15–44 use contraception. Almost half of those use either short- or long-acting hormonal oral contraceptive pills or devices such as a ring or a patch. According to Evaluate Pharma, $6.5bn worth of hormonal contraceptives were sold in 2018.

Positive data indicative of efficacy

Two large Phase III trials have been conducted with Amphora. In 2014, the company reported that the 3,389-patient AMP001 trial met the primary endpoint of non-inferiority to Conceptrol, a spermicidal gel. The FDA issued a complete response letter in 2016 as it questioned some of the data from Russia (20% of the trial participants) so the company initiated the 1,400-patient confirmatory AMPOWER trial, which recently met its primary endpoint.

Valuation: $816m or $6.37 per share

We have increased our valuation to $816m or $6.37 per basic share, from $757m or $5.91 per share. The increase is due to adding the value of the Evofem investment, net of the $30m cash from the first tranche. We estimate that Amphora will be able to achieve $521m in peak sales with patent protection out to 2033.

16 April 2019

Price	**US$3.81**
Market cap	**US$488m**

Net cash ($m) at 31 December 2018	244.6
Shares in issue	128.1m
Free float	91.9%
Code	PDLI
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	7.0	20.3	26.7
Rel (local)	4.0	8.0	15.8

52-week high/low	US$3.85	US$2.28

Business description

PDL BioPharma currently has a collection of healthcare-related royalty and note assets as well as Tekturna/Rasilez for hypertension. PDL is seeking additional commercial-stage pharmaceutical assets with multiple-year revenue growth potential, as well as late clinical-stage pharmaceutical products.

Next events

China Rasilez launch	H119
Evofem NDA filing	H219

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Edison profile page

Investing in women's health

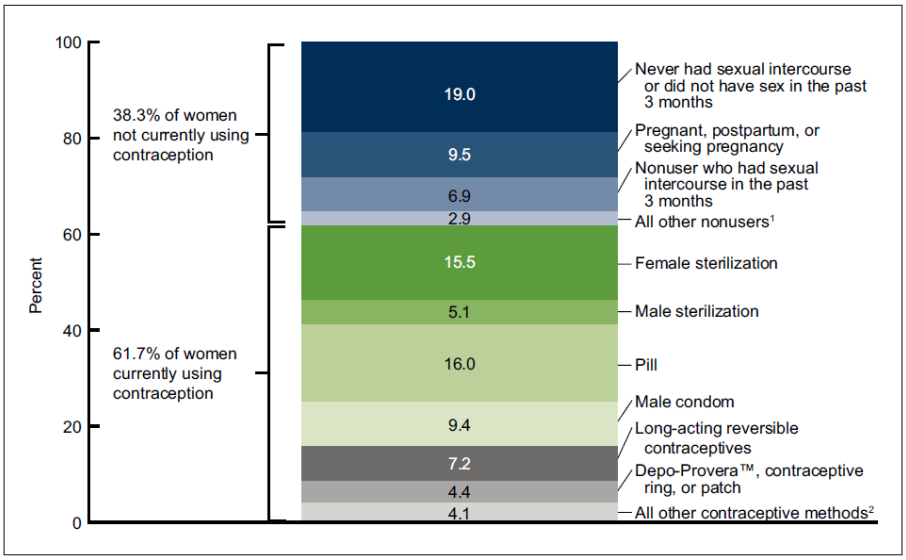
PDL has announced that it entered into a securities purchase agreement with Evofem, a Nasdaq-listed women's health company that is developing a non-hormonal contraceptive product. PDL will invest up to $60m in two tranches of $30m each, the first being invested immediately and the second being invested by 10 June 2019. Both tranches will have the same terms, a purchase price of $4.50 per share (a 26% premium to the closing price of Evofem the day before the investment was announced) for 6,666,667 shares with 1,666,667 warrants with an exercise price of $6.38 per share. Additionally, Woodford, which owns 9.6m shares (~34% of the company pre-PDL deal) of the company, and Invesco, which owns 9.2m shares (~33% of the company pre-PDL deal), have an opportunity to invest up to $10m each at the same terms as PDL. Following the investment of the first tranche, PDL owns approximately 19% of the company and will own 29% of Evofem assuming it, Woodford and Invesco all exercise their rights to invest in the second tranche. The company had previously indicated that it was looking at pre-commercial opportunities and this fits in well with that. The structure is especially appealing as it does provide the promise of substantial returns but with downside capped at either $30m or $60m if Evofem does not live up to expectations.

The Evofem opportunity

Evofem is developing Amphora as a contraceptive. Amphora is bioadhesive vaginal gel that is a mix of L-lactic acid, citric acid and potassium bitartrate, all compounds that are considered to be generally regarded as safe (GRAS) by the FDA and are frequent ingredients in food. Amphora works by maintaining the vaginal pH level in the 3.5–4.5 range, which is mildly acidic and inhospitable to sperm, which requires a more neutral pH environment for optimum mobility. Typically, semen, with a pH of 7.2–8.0, helps to raise the pH of the vaginal environment to 6.0 or higher. Data indicate that Amphora is effective if applied up to 10 hours prior to intercourse.

The addressable market is quite large. According to the CDC, 61.7% of the 60.9 million women aged 15–44 use contraception and 27.6% (around 16.8 million) use either short- or long-acting hormonal oral contraceptive pills or devices such as a ring or a patch.

Exhibit 1: Contraception method share in women aged 15–44



Source: CDC, National Center for Health Statistics, Data Brief number 173, December 2014

According to Evaluate Pharma, $6.5bn worth of hormonal contraceptives were sold in 2018 and importantly many still have meaningful sales despite being on the market for two to three decades and being off patent (see Exhibit 2). While generics exist, brand is important in this market.

Exhibit 2: Select marketed hormonal contraceptive products

Product	Generic name	Company	Launch year	Patent expiry	2018 sales ($m)
Mirena	levonorgestrel	Bayer	1990	Dec 2015	1,350
Nexplanon	etonogestrel	Merck & Co	1998	Sep 2009	703
Lo Loestrin FE	ethinyl estradiol; ferrous fumarate; norethindrone acetate	Allergan	2011	Feb 2029	528
Yasmin	drospirenone; ethinyl estradiol	Bayer	2000	May 2008	755
NuvaRing (vaginal ring)	ethinyl estradiol; etonogestrel	Merck & Co	2002	Apr 2018	902

Source: Evaluate Pharma

However, despite the popularity of hormonal contraceptives, they are associated with some potential severe side effects. The risk of venous thromboembolism increases three to six times, while the risks of heart attack or stroke go up two to three times[1]. Also, certain women are contraindicated from receiving hormonal therapy, including smokers over the age of 35 and women with a history of breast or pelvic cancers. Hence a safe and effective alternative to hormones would likely find a market, likely a mix of some switching over from hormonal therapy and those who are currently not using contraception.

Amphora's efficacy was demonstrated in two large Phase III trials. In 2014, the company reported that the 3,389 patient AMP001 trial met the primary endpoint of non-inferiority to Conceptrol, a spermicidal gel. In the modified intent to treat analysis, the cumulative pregnancy percentage was 10.5% in the Amphora arm and 10.0% in the Conceptrol arm. For the "perfect use" population (defined as those who used their assigned product for every sexual episode), the pregnancy percentage was 4.1% in the Amphora arm compared to 4.2% with Conceptrol. Importantly, Amphora demonstrated a benign safety profile with fewer than 2% of women withdrawing due to an adverse event, a slightly lower rate than with Conceptrol.

However, the FDA had some issues with the data, namely from the 20% of study participants in Russia, which the agency viewed as "not generalizable" to the US population and requested a confirmatory trial. Following feedback from the FDA, the company initiated the 1,400-patient confirmatory AMPOWER trial, which would be conducted exclusively in the United States with a pre-specified hurdle of a seven-cycle pregnancy rate of 16.5% with an upper limit of the confidence interval at 21%. In December 2018, Evofem announced the results of the AMPOWER trial and that it met the primary endpoint with a seven-cycle cumulative pregnancy probability of 14% with the upper limit of the confidence interval at 18%. In women who used Amphora perfectly (per patient reporting), the cumulative pregnancy rate was only 1.3%. Once again, the adverse event profile was clean with fewer than 2% withdrawing due to an adverse event.

Evofem is currently expected to re-file on this data in H219, which, assuming a six-month review (as it is not this product's first cycle before the FDA), means approval in H120. The company plans to launch with 100 salespeople, which would allow it to target the top 30% of contraception prescribing physicians (the vast majority of whom are gynaecologists). According to market research conducted by the company, its expectation are for a warm reception with Amphora potentially becoming the second most popular birth control method (see Exhibit 3). We view this as a bit aggressive as surveys often overshoot reality and people historically are reluctant to change practices, but Amphora's market reach does not need to be this large for the PDL investment to be successful.

1 Gorenoi et al, Benefits and risks of hormonal contraception in women. German Medical Science Health Technology Assessment 2007, Vol. 3

Exhibit 3: Survey results of 1,024 healthcare practitioners on anticipated market share post-Amphora approval

Method	Share post-Amphora approval	Relative change
Oral contraceptives (28-day)	26%	-14%
Amphora	15%	N/A
Hormonal IUD	11%	-10%
Condom	8%	-20%
Injectables	7%	-15%
Oral contraceptives (extended)	7%	-15%
None	5%	-19%
Implant	5%	-12%
Non-hormonal IUD	4%	-11%
Vaginal ring	4%	-14%
Fertility awareness	3%	-19%
Patch	3%	-18%
Emergency contraception	1%	-20%
Diaphragm/spermicide/cervical cap/sponge	1%	-16%
Other	0%	-13%

Source: Evofem

With regards to price, Evofem expects to price Amphora at $100–200 per month, which will likely not pose too much of a problem in getting insurance coverage. Also, as a reminder, minimum coverage requirements dictated by the Affordable Care Act (ACA) require most private healthcare plans to cover at least one form of each of the 18 FDA-approved contraceptive methods for women at no cost to the covered individual. So there is a bit of a political/regulatory tailwind that should assist Evofem in getting coverage.

Valuation

We have increased our valuation from $757m or $5.91 per basic share to $816m or $6.37 per share. The increase is due to adding the value of the Evofem investment, net of the $30m cash from the first tranche, which gives PDL a 19% position in the company. To value Evofem, we used a risk-adjusted NPV model and a 12.5% discount rate. Although both the Phase III trials were positive, we attribute a 70% chance of success to the product, slightly below our standard 80–90% in these situations. The reasons for the discount are that the FDA had previously had issues with the data from the first Phase III trial and this is not a huge unmet medical need.

We assume a price per patient of $150 per month with peak sales reaching up to $521m at expected patent expiration in 2033. With regards to the intellectual property position, there are currently granted patents that cover Amphora that expire in 2021, though the company believes these can be extended to at least 2024 through a Hatch-Waxman patent extension. In addition, Evofem also has the rights to several patent application families that would protect the product through 2033, if granted. There is also the question of how a generic would be approved as it is unclear how to demonstrate bioequivalence to a product like Amphora. It is possible that no generic is currently possible and a competitor would need to run clinical studies with their own version once patents expire (though the studies may be smaller than those run by Evofem). Without a substitutable generic and given current contraceptives have been able to maintain meaningful sales even with generics, modelling to 2033 may prove conservative.

We expect to update our valuation further once the second tranche is finalized and following regulatory updates from Evofem.

Exhibit 4: PDL valuation table

Royalty/Note	Type	Expiration year	PDL balance sheet carrying value ($m)	NPV ($m)
Assertio (formerly Depomed)	Royalty on Glumetza and other products	2024	$264.4	$271.1
VB	Royalty on Spine Implant	Undisclosed	$14.1	$14.7
University of Michigan	Royalty on Cerdelga	2022	$25.6	$12.8
Wellstat	Note (Impaired)	Unknown	$50.2	$50.2
Hyperion	Note (impaired)	Unknown	$1.2	$1.2
Lensar	Equity		N/A	$56.2
AcelRx	Royalty on Zalviso	2027	$70.4	$73.7
CareView	Note (impaired)	2022	$11.5	$11.5
Noden	Equity	N/A	$37.6	$19.9
Kybella	Royalty	Unknown	$2.7	$0.8
Evofem	Equity	N/A	N/A	$89.0
Total				$601
Net cash (Q418 less Evofem investment) ($m)				$214.6
Total firm value ($m)				**$816**
Total basic shares (m)				128.1
Value per basic share ($)				**$6.37**
Total options (m)				1.4
Total number of shares (m)				129.5
Diluted value per share ($)				$6.30

Source: Edison Investment Research

Financials

The company ended Q418 with $394.6m in cash ($244.6m in net cash) so even with a full investment of the two tranches into Evofem, PDL will have a substantial amount of cash to execute on its business plans, which may include additional investments.

Exhibit 5: Financial summary

$000s	2017	2018	2019e	2020e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	320,060	198,110	122,504	124,544
Cost of Sales	(30,537)	(48,460)	(29,060)	(29,348)
Gross Profit	289,523	149,650	93,445	95,197
General & Administrative	(63,324)	(62,559)	(35,164)	(36,571)
EBITDA	218,818	84,136	55,326	55,671
Operating Profit (before amort. and except.)	218,818	84,136	55,326	55,671
Intangible Amortisation	(24,689)	(15,831)	(15,831)	(15,831)
Other	0	0	0	0
Exceptionals	(349)	(118,899)	0	0
Operating Profit	193,780	(50,594)	39,495	39,840
Net Interest	(18,562)	(5,328)	3,387	4,138
Other	9,309	0	0	0
Profit Before Tax (norm)	200,256	78,808	58,713	59,809
Profit Before Tax (FRS 3)	184,527	(55,922)	42,882	43,978
Tax	(73,826)	(12,937)	(9,005)	(9,235)
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	126,430	65,871	49,707	50,574
Profit After Tax (FRS 3)	110,701	(68,859)	33,876	34,743
Minority interest	(47)	0	0	0
Profit After Tax less Minority Interest (FRS 3)	110,654	(68,859)	33,876	34,743
Average Number of Shares Outstanding (m)	155.4	145.7	129.9	135.1
EPS - normalised ($)	0.81	0.45	0.38	0.37
EPS - FRS 3 ($)	0.71	(0.47)	0.26	0.26
Dividend per share (c)	0.00	0.00	0.00	0.00
Gross Margin (%)	90.5	75.5	76.3	76.4
EBITDA Margin (%)	68.4	42.5	45.2	44.7
Operating Margin (before GW and except.) (%)	68.4	42.5	45.2	44.7
BALANCE SHEET				
Fixed Assets	602,680	446,519	370,011	320,082
Intangible Assets	215,823	51,319	51,319	51,319
Tangible Assets	7,222	7,387	8,612	9,857
Royalty rights	349,223	376,510	271,087	219,912
Other	30,412	11,303	38,993	38,993
Current Assets	640,443	517,217	600,202	715,296
Stocks	0	0	0	0
Debtors	31,183	21,648	21,648	21,648
Cash	527,266	394,590	477,575	592,669
Other	81,994	100,979	100,979	100,979
Current Liabilities	(193,109)	(52,470)	(52,470)	(52,454)
Creditors	(19,785)	(13,142)	(13,142)	(13,142)
Short term borrowings	(126,066)	0	0	0
Other	(47,258)	(39,328)	(39,328)	(39,312)
Long Term Liabilities	(204,124)	(181,487)	(181,487)	(181,487)
Long term borrowings	(117,415)	(124,644)	(124,644)	(124,644)
Other long term liabilities	(86,709)	(56,843)	(56,843)	(56,843)
Net Assets	845,890	729,779	736,257	801,437
Minority Interests	0	0	0	0
Shareholder equity	845,890	729,779	736,257	801,437
CASH FLOW				
Operating Cash Flow	40,624	(13,425)	14,500	13,990
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(1,297)	(4,523)	(1,225)	(1,245)
Acquisitions/disposals	128,415	57,969	99,710	102,350
Financing	0	0	0	0
Dividends	(222)	(48)	0	0
Other	212,592	(46,202)	(30,000)	0
Net Cash Flow	380,112	(6,229)	82,985	115,094
Opening net debt/(cash)	85,289	(283,785)	(269,946)	(352,931)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	(11,038)	(7,610)	0	0
Closing net debt/(cash)	(283,785)	(269,946)	(352,931)	(468,025)

Source: Edison Investment Research, PDL BioPharma reports

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