EOLS Evolus Inc. (NASDAQ:EOLS)

January 25, 2019

SUMMARY

Sana Currents forecasts a high pivotal sentiment that EOLS Evolus Inc.'s (NASDAQ:EOLS) lead candidate DWP-450, a 900 kDa purified botulinum toxin type A complex, will receive FDA approval to treat moderate-to-severe glabellar lines in adult patients under 65 years of age.

If approved by its PDUFA date of February 2, 2019, DWP-450, recently branded as Jeuveau, could become a significant competitor in a market long monopolized by Allergan's [NYSE:AGN] Botox kDA. DWP-450 is the first molecular size-specific 900 kDA toxin to be developed since Botox.

Evolus received a complete response letter (CRL) from the FDA on May 15, 2018 regarding its biologic license application (BLA) for DWP-450.

Even though Evolus warned in early 2018 it had received 10 critical observations from an FDA inspection of its Daewoong Pharmaceuticals manufacturing facility in Korea, the FDA signed off on its pre-approval inspection of the Daewoong plant. In the CRL, however, the FDA said the Evolus' BLA was not sufficient for approval as originally submitted due to a number of cited deficiencies. The deficiencies related to Chemistry, Manufacturing, and Controls, or CMC processes, not to clinical submissions or the facility.

Evolus responded to the FDA, as promised, by August 2018. The FDA then assigned the February PDUFA date.

Neither Evolus nor the FDA has been expansive on the nature of the cited CMC deficiencies in the original BLA submission, but the manufacturing of botulinum toxins is tricky. Upon the introduction of Galderma/Ipsen's Dysport, a different-sized competitor to Botox, a scientific journal noted not all botulinum toxins should be considered "equivalent formulations because they have … different isolation and manufacturing processes that result in unique product characteristics." Mylan NV [NASDAQ:MYL], an experienced drug manufacturer, recently decided not to manufacture its internal botulinum toxin program and instead partnered with another company to develop the drug.

In introducing the first competitor to Botox, Evolus likely had a high CMC bar to establish its specific isolation and manufacturing processes, leading to the initial CRL. The FDA has since advanced Jeuveau with three decisions: Approving the Daewoong facility; accepting the company's response to the original CRL and providing the PDUFA date; and signing off on the brand name Jeuveau, a requirement prior to launching a new drug or biologic.

If the government shutdown does not delay a decision on the February 2 PDUFA date, the FDA's recent actions point to final approval for Jeuveau. Evolus plans to launch the drug shortly thereafter.

PROBABILITY SENTIMENT

Pivotal

Key Catalyst(s)

- FDA Approval For DWP-450

Key Catalyst Date(s)

- February 2, 2019

Insider & Institutional Holdings

- 56.52% % of Shares Held by All Insider
- 24.67% % of Shares Held by Institutions
- 56.74% % of Float Held by Institutions
- 97 Number of Institutions Holding Shares

Location

17901 Von Karman Avenue
Suite 150
Irvine, CA 92614
United States

Executives

Dr. Rui Avelar M.D., Chief Medical Officer & Head of R&D

Mr. David Moatazedi, Pres ,CEO & Director

Ms. Lauren P. Silvernail, CFO & Exec. VP of Corp. Devel.

Mr. Alejandro Sabad, VP of Operations

Jeffrey J. Plumer, VP of Legal

Website

https://www.evolus.com/

EOLS Evolus Inc. (NASDAQ:EOLS) Probability Sentiment

THE EDGE

Evolus replaced its CEO on May 10 when David Moatazedi, a former SVP of US Medical Aesthetics at Allergan, took the helm. Investors widely applauded the appointment, regarding Moatazedi as more experienced to lead the marketing of Jeuveau against Allergan and the two other key competitors (Galdrema/Ipsen and Merz). In addition to receiving a stock boost by the appointment of Moatazedi, Evolus was able to minimize the effect of the CRL, disclosed by the company on May 16.

The timing of Moatazedi's appointment signifies Evolus initiated necessary action to correct the company's simmering regulatory problems. Moatazedi since has added several new executives to prepare for the launch of Jeuveau and apparently has corrected the course of the BLA.

Unbeknownst to most investors, Botox is approved for both therapeutic and aesthetics indications. In contrast, DWP-450 is only seeking approval for aesthetics indications. This normally would be viewed as a disadvantage, especially since it limits DWP-450 addressable markets, but it actually could be a positive due to pricing. Because DWP-450 is solely focused on receiving approval for aesthetics indications, DWP-450 is likely to be priced at a significant discount (20-25%) to Botox.

A price discount alone isn't enough to convince doctors to prescribe another competing drug. The drug has to be just as effective as the original. DWP-450 also meets such criteria, and has demonstrated non-inferiority to Botox in several phase III trials. In fact, an 87.2% response rate improvement was observed in patients undergoing DWP-450 treatments. Botox on the other hand only posted an 82.8% response rate.

Another tailwind DWP-450 has going for it is many key opinion leaders in dermatology and plastic surgery are invested in the parent company, Alphaeon.

In August 2018, Health Canada approved marketing of DWP-450 to treat moderate to severe glabellar lines in Canada, the same indication Evolus wants the FDA to approve.

The global self-pay medical aesthetics market is expected to generate more than $1.8 billion in revenue in 2019 and could reach $2.3 billion by 2020. The US market expected to generate the most growth.

With Botox, Allergan controls 70% of the US market, according to Evolus. Galderma/Ipsen's Dysport owns 20.5%, while Merz's Xeomin, a smaller molecular weight, has 9.5% market share.

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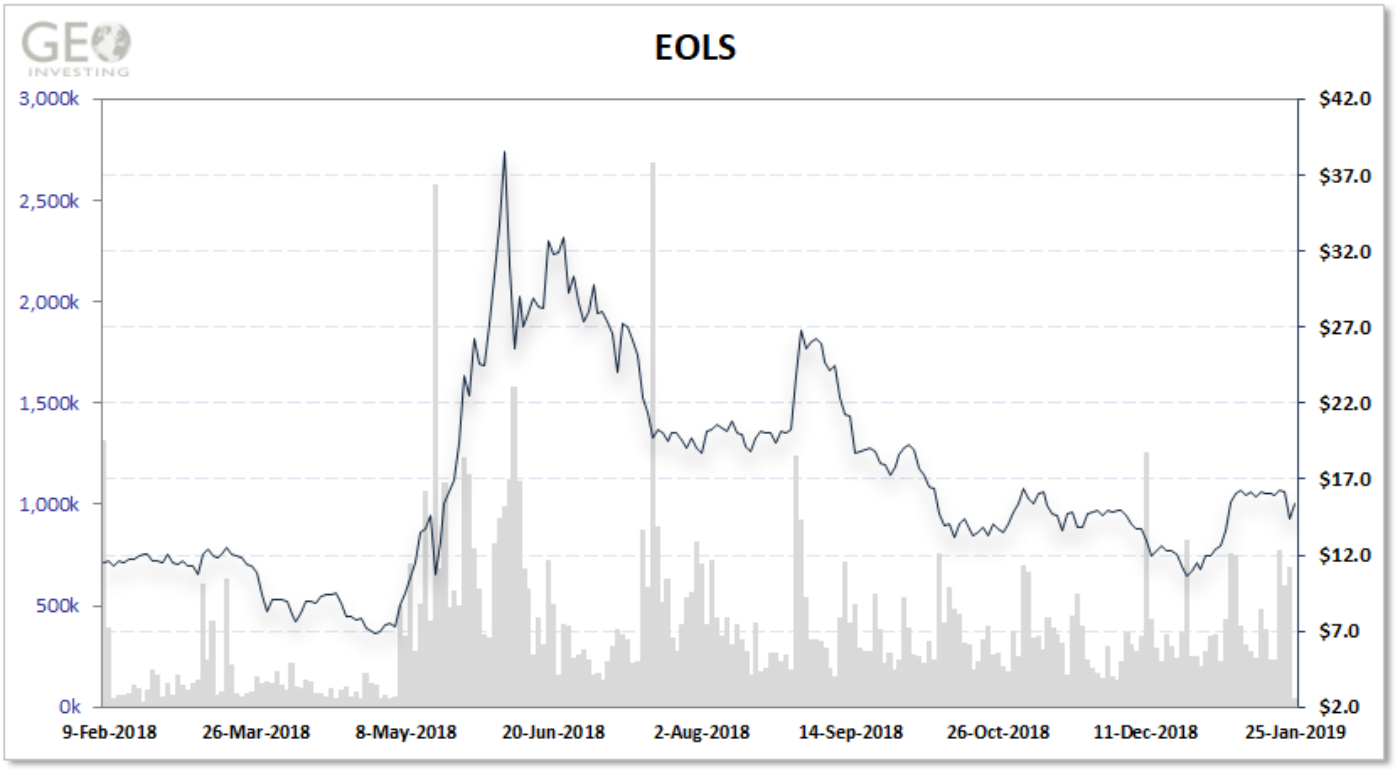

Evolus, Inc. **(EOLS)** data provided by Sentieo

Evolus, Inc. is a medical aesthetics company. The Company is focused on providing physicians and aesthetic procedures and treatments. It also focuses on offering the self-pay aesthetic market and its product candidate, PrabotulinumtoxinA (DWP-450), is an injectable 900 kilodalton, or kDa, botulinum toxin type designed to address the needs of the large and growing facial aesthetics market. It offers physicians and patients a compelling value proposition with DWP-450. OnabotulinumtoxinA (BOTOX) is the neurotoxin approved 900 kDa botulinum toxin type A complex in the United States.

GICS Sector	Pharmaceuticals
GICS Industry	Health Care
Next FQ/FH End Date	12/31/2018
Next FY End Date	12/31/2018
Next Earnings Date	
Latest Earnings Date	11/05/2018

*in millions USD, except per share data

Market Cap	*392.49*
EV	*304.11*
Shares Outstandin	*27.27*
Annual Dividend	*0.00*
Dividend Yield	*0.00*
Dividend Payout	*0.0%*

FIN. SUMMARY

Period end	*12/31/2017*	*12/31/2018*	*12/31/2019*
Revenue	0.000	0.000	19.765
Gross Profit	0.000	0.000	10.579
Gross Margin		*-150.0%*	*53.5%*
Operating Profit	(11.73)	(49.72)	(81.35)
Operating Margin			*-411.6%*
Net Income	-5.10	-50.84	-82.11
EPS	-0.31	-2.12	-3.04

VALUATION RATIOS

	12/31/2018
EV/Sales	
EV/EBITDA	-5.97 x
P/E	-6.79 x
P/B	
FCF Yield	

STOCK PRICE PERFORMANCE*

As of	1/25/2019
Last price	15.40
52 Week High	39.50
52 Week Low	6.75
YTD Change	15.8%
1 Year Change	
5 Year Change	
10 Year Change	

TICKER	DRUG	STAGE	CATALYST
EOLS	**DWP-450** Glabellar lines	PDUFA	02/02/2019 CRL announced May 16, 2018. New PDUFA date February 2, 2018.

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