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Zacks Small-Cap Research

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Aevi Genomic Medicine (GNMX-NASDAQ)

'001' Discontinued After ASCEND Misses Primary Endpoint, Focus Is Now On '002'

We have built a DCF using $2.1B as peak sales in year 10 post-launch. We assume launch in 2025 and AEVI-002 garners 5% share in its first year on the market. This implies a revenue CAGR of ~35% from launch until peak sales in year 10. We further assume net cash margins of 35%. If we discount this back to the present at 11% and assume just 5% probability of successful development, regulatory approval and commercialization, this values AEVI-002 at approximately $0.50/share.

Current Price (04/10/19)	$0.21
Valuation	**$0.50**

OUTLOOK

On January 2nd Aevi announced that ASCEND, the phase II trial evaluating their non-stimulant glutamatergic neuromodulator in pediatric and adolescent subjects with ADHD, failed to meet its primary endpoint of a statistically significant reduction of ADHD-RS at 6 weeks in either Part A (mGluR+ subjects) or Part B (mutation free subjects). AEVI-001 was safe and well tolerated.

While GNMX's press release announcing the results mentioned that the company "remains committed to the development of AEVI-001 as a potential treatment for a sub-population of ADHD patients with genetic mutations that disrupt the mGluR network", language in the 10-K (filed March 29, 2019) makes it clear that this program has now been discontinued. Specifically, given "the negative outcomes of the ASCEND trial, we have terminated the AEVI-001 program." Based on the 10-K, Aevi indicates that they intend to continue to forge ahead with their other programs, including AEVI-002 in severe pediatric-onset Crohn's Disease, which could have topline data near the middle of this year.

SUMMARY DATA

52-Week High	**$1.86**
52-Week Low	**$0.19**
One-Year Return (%)	**-88.69**
Beta	**0.32**
Average Daily Volume (sh)	**1,924,399**
Shares Outstanding (mil)	**65**
Market Capitalization ($mil)	**$13**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**19**
Insider Ownership (%)	**12**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0 A	0 A	0 A	0 A	0 A
2019					0 E
2020					0 E
2021					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.15 A	-$0.14 A	-$0.12 A	-$0.10 A	-$0.50 A
2019	-$0.10 E	-$0.10 E	-$0.05 E	-$0.05 E	-$0.27 E
2020					-$0.18 E
2021					-$0.18 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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Q4 2018 Results / Business Update

Aevi filed their 10-K for the year ending December 31, 2018. Relative to the financials, Q4 operating expenses were $6.7M, down from $7.2M in the year-earlier period and from $7.3M in Q3'18. Both G&A and R&D expenses were at multi-year lows. Q4 G&A expense of $1.8M was down about 5% on a yearly basis, down 17% sequentially and the lowest level since Q2 2013. Meanwhile, R&D expense fell 8% yoy and 5% qoq to $4.9M, the lowest since Q4 2015.

Cash used in operating activities was $7.5M and $26.7M ($5.8M and $27.6M, ex-changes in working capital) in the three and twelve months ending December 31, 2018, compared to $8.3M and $33.2M ($6.4M and $31.2M, ex-changes in working capital) in the comparable prior-year periods.

Cash balance was $12.0M at 2018 year-end and was $8.3M on February 28, 2019 (per disclosure in the 10-K). Management anticipates current cash to be sufficient to fund operations through early-Q3 of this year. Per an agreement signed on March 25th, 2019 monthly payments under the CHOP research agreement have been deferred through September 30th. In exchange, CHOP received a non-interest-bearing note for the deferral amount which matures on September 30th and is payable, at CHOP's option, in cash or the number of shares equal to the deferral amount based on the price of the common stock at that time.

Operational Update: *'001' discontinued after ASCEND misses primary endpoint, focus is now on '002'*

On January 2nd Aevi announced that ASCEND, the phase II trial evaluating their non-stimulant glutamatergic neuromodulator in pediatric and adolescent subjects with ADHD, failed to meet its primary endpoint of a statistically significant reduction of ADHD-RS at 6 weeks in either Part A (mGluR+ subjects) or Part B (mutation free subjects). AEVI-001 was safe and well tolerated.

Aevi did not provide detailed results, including what the outcomes were of the secondary endpoints; CGI-I, ADHD-RS inattention subscale, ADHD-RS responder and CGI-I responder. However, the January 2nd press release did note that, following a full review of the data, the company will "consider their options." As we explained in our January 21st Investor Note, given the largely positive results of SAGA and enrichment of ASCEND with only patients with mutations to nine select genes in the mGluR network, along with a pediatric weighting, we were surprised by the outcome.

While GNMX's press release announcing the results mentioned that the company "remains committed to the development of AEVI-001 as a potential treatment for a sub-population of ADHD patients with genetic mutations that disrupt the mGluR network", language in the 10-K (filed March 29, 2019) makes it clear that this program has now been discontinued. Specifically, given "the negative outcomes of the ASCEND trial, we have terminated the AEVI-001 program."

AEVI-002 (severe pediatric Crohn's): *initial proof-of-concept data may be available ~mid-2019*

Based on the 10-K, Aevi indicates that they intend to continue to forge ahead with their other programs, including AEVI-002 in severe pediatric-onset Crohn's Disease and AEVI-005 a first-in-class monoclonal antibody targeting an undisclosed autoimmune ultra-orphan pediatric disease.

The AEVI-002 program relates to patients with severe pediatric onset IBD with or without DcR3 loss-of-function mutations (10% - 15% of pediatric onset Crohn's patients have this DcR3 mutation) and which have failed anti-TNF alpha therapy. This is anticipated to be an orphan designation. Anticipated to enroll 8 to 12 patients over the age of 18, AEVI-002 will be administered in one of two doses (1.0mg/kg or 3.0 mg/kg) via subcutaneous injection for 14 days. Clinical endpoints are endoscopic evaluation (i.e. healing) and the Crohn's Disease Activity Index. Aevi will use the topline data to decide whether to continue development (via their license with Kirin).

As a reminder, this Anti-LIGHT program in pediatric onset Crohn's (AEVI-002) has been plagued by persistent delays due to extreme difficulties in recruiting and enrolling patients. While screening at the primary site (CHOP IBD center) commenced in June 2017 and three additional sites were subsequently activated (Salt Lake City, Emory and Vanderbilt) in an attempt to facilitate enrollment, no patients have yet to enroll in the study. GNMX has noted that if enrollment commences by the end of Q1 '19, that initial data from a small number of patients may be available by mid-2019. However, that timeline could slip further depending on if there's any traction on enrolling patients.

AEVI-005
GNMX exercised their option under their existing agreement with Kyowa Hakko Kirin (i.e. related to their anti-LIGHT candidate), licensing rights to 'AEVI-005. Citing competitive reasons, specifics regarding the compound ('first in-class monoclonal antibody'), target ('specific cell-surface marker) and disease/condition ('autoimmune ultra-orphan pediatric disease as well as larger adult orphan diseases') have yet to be disclosed. Currently in preclinical development stage. Preclinical research commenced in Q2 '18.

Exploring 'strategic options'
The failure of AEVI-001 has also prompted the company to explore strategic options. Per the 10-K, "In light of our decision to discontinue the AEVI-001 program in ADHD, our board of directors has commenced a review to explore and evaluate potential strategic alternatives to enhance stockholder value. These alternatives could include, among others, continuing to execute the Company's business plan, issuing or transferring shares of our common stock or other equity securities, the license, sale or disposition of certain assets or programs, the formation of a joint venture, a strategic business combination, a transaction that results in private ownership or the sale of the Company, or some combination of these."

VALUATION:
Approximately 780k Americans suffer from Crohn's disease, ~15% of which are believed to have early onset. This puts the U.S. market for AEVI-002 at no more than 117k people and potentially significant less if only including those that have failed anti-TNF alpha therapy. This should qualify AEVI-002 for orphan eligibility.

According to Evaluate Pharma the average cost per patient per year of an orphan drug (for all indications) is approximately $140k.[1] If we assume the 'average' orphan drug has four approved indications, this means the cost per patient per indication per year of an average orphan drug is approximately $35k.

Assuming an estimated U.S. target market of 60k people and applying the ~$35k average cost per patient per year of an orphan drug, means the potential market for AEVI-002 (for the single indication of severe pediatric onset Crohn's and refractory to anti-TNF alpha therapy) could be worth more than $2B. While we are not suggesting that AEVI-002, if successfully developed and approved, will eventually generate this level of sales, we think the calculation is relevant in the context of the potential of AEVI-002.

We have built a DCF using $2.1B as peak sales in year 10 post-launch. We assume launch in 2025 and AEVI-002 garners 5% share in its first year on the market. This implies a revenue CAGR of ~35% from launch until peak sales in year 10. We further assume net cash margins of 35%. If we discount this back to the present at 11% and assume just 5% probability of successful development, regulatory approval and commercialization, this values AEVI-002 at approximately $0.50/share.

These are admittedly broad and rough calculations – but also arguably conservative as it relates to the inputs of our DCF and overall potential of AEVI-002. We have also not included any potential value of AEVI-005 in our calculated firm value of GNMX – development progress of which could offer upside.

Given the failure of AEVI-001 and subsequent decision by GNMX to discontinue that program, our price target has moved from $1.00 to $0.50/share. Our assumptions will be updated if and when warranted.

[1] Evaluate Pharma, Orphan Drug Report 2017

FINANCIAL MODEL

Aevi Genomic Medicine, Inc.

	2018 A	Q1E	Q2E	Q3E	Q4E	2019 E	2020 E	2021 E
Total Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Margin	-	-	-	-	-	-	-	-
SG&A	$8,663.0	$1,848.7	$1,857.4	$1,832.9	$1,648.8	$7,187.8	$8,080.9	$8,841.3
% SG&A	-	-	-	-	-	-	-	*20.0%*
R&D, net of grants	$22,299.0	$4,654.5	$4,341.1	$4,287.8	$4,677.2	$17,960.6	$19,617.4	$21,558.7
% R&D	-	-	-	-	-	-	-	-
Operating Income	($30,962.0)	($6,503.2)	($6,198.5)	($6,120.7)	($6,326.0)	($25,148.4)	($27,698.3)	($30,400.0)
Operating Margin		-	-	-	-	-	-	-
Financial income, net	$187.0	$32.0	$14.5	$5.1	$1.2	$52.8	$84.7	$71.2
Total Other Income (Expense)	$187.0	$32.0	$14.5	$5.1	$1.2	$52.8	$84.7	$71.2
Pre-Tax Income	($30,775.0)	($6,471.2)	($6,184.0)	($6,115.6)	($6,324.8)	($25,095.6)	($27,613.6)	($30,328.8)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($30,775.0)	($6,471.2)	($6,184.0)	($6,115.6)	($6,324.8)	($25,095.6)	($27,613.6)	($30,328.8)
YOY Growth	*-11.3%*	*-81.4%*	*-29.0%*	*-25.3%*	*-12.7%*	*-18.5%*	*10.0%*	*9.8%*
Net Margin	-	-	-	-	-	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
EPS	($0.50)	($0.10)	($0.10)	($0.05)	($0.05)	($0.27)	($0.18)	($0.18)
YOY Growth	*-39.8%*	*-33.9%*	*-36.4%*	*-63.7%*	*-10.3%*	*-46.3%*	*-32.5%*	*1.2%*
Diluted Shares O/S	61,382	64,767	64,767	118,200	125,400	93,284	152,000	165,000

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