

DNA Biomedical Solutions Ltd.: Preparations for pre-IND (505(b) (2) submission and expected capital raising by Entera; BeamMed retains a similar sales rate with a growing presence in the US; Target price remains unchanged.

Primary Exchange: TASE

Ticker: TLV: DNA

Sector: Healthcare

Industries: Biotechnology and Medical Devices

Data as at 10 April, 2018

(Source: TASE)

Closing price: NIS 0.25

Market cap: NIS 37.6M

of shares: 147,606,627

Stock performance (Y.T.D.): -17.9%

Daily-trading-vol. (12 mos.): NIS 378.5K

Stock target price: NIS 0.79

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Company Overview

Israeli holdings firm **DNA Biomedical Solutions Ltd.** (hereinafter 'DNA', 'DNA Biomed' or 'the Company') was founded in 2004 and went public on the Tel Aviv Stock Exchange (TLV: DNA) in 2007. DNA has two key holdings, respective 35% and 40% stakes (both fully diluted) in biomedical companies - *Entera Bio* and *BeamMed*.

Entera Bio Ltd. (hereinafter 'Entera') is a drug development company, founded in 2009 by DNA and Oramed (TASE/NASDAQ: ORMP), the latter from whom it has licensed a unique drug delivery platform for oral administration of pharmaceutically active large molecule proteins that are nowadays injected. *Entera* is conducting clinical trials for two candidate drugs treating three indications: hypoparathyroidism, osteoporosis, and non-union fractures.

BeamMed Ltd. (hereinafter 'BeamMed') and its global subsidiaries, are medical device companies that deliver an ultrasound based screening solution for determining a patient's risk of developing osteoporosis, with unique additional product features. They have established themselves in the screening stage of the osteoporosis therapy value chain. Their product utilizes ultrasonically measurable parameters as the basis of a patient's risk factor. After initial success in East Asia, they are now looking to expand their US sales.

Highlights & Analysis

DNA released its annual report for 2017 detailing the following:

Entera Bio continues its efforts to raise capital; and plans to submit a pre-IND to the FDA (505(b) (2) regulatory path) for the EB613

- At December 31, 2017 Entera had an operating loss of approximately \$11.3M, an increase of approx. \$6M compared to 2016, which occurred due to the costs of registration to the NASDAQ and related expenses.
- On January 26, 2018, Entera Bio informed DNA that it had not completed the process of issuing and listing the shares for trading as it had planned. **In our opinion, the effect of the non-completed offering on Entera's development plans is immaterial.**
- Entera also plans to submit a pre-IND to the FDA to be considered under the 505(b) (2) regulatory pathway for EB613. If Entera will receive FDA approval, it will have a significant positive effect on the drug's time to market. Currently, the Company is expected to initiate Phase 2b/3 trials, with their EB612 PTH 1-34 for hypoparathyroidism in H2-2018.
- Financially, it should be noted that Entera recently completed a \$13M financing round, and therefore, in our opinion, at present, the Company has sufficient funding to complete the necessary preparations prior to initiating the aforementioned experiments.
- At the same time, we expect Entera to try and raise public and/or private capital in the coming months. If Entera raises sufficient capital, there should be no delay in its clinical development program.

BeamMed retained its sales pace, with a key focus on penetrating the US market

- Revenues totaled NIS 12M at December 31, 2017, similar to 2016, with a high proportion of sales coming from Asia, and NIS 900K from the US.
- BeamMed's sales show a certain change in the sales mix with sales growing in the USA compared to 2016.
- Sales and marketing expenses for 2017 increased by NIS 200,000 from 2016.

We keep DNA's value at approximately \$30.9 million (NIS 108.7M) corresponding to a target price of \$0.23 (NIS 0.79) per share.

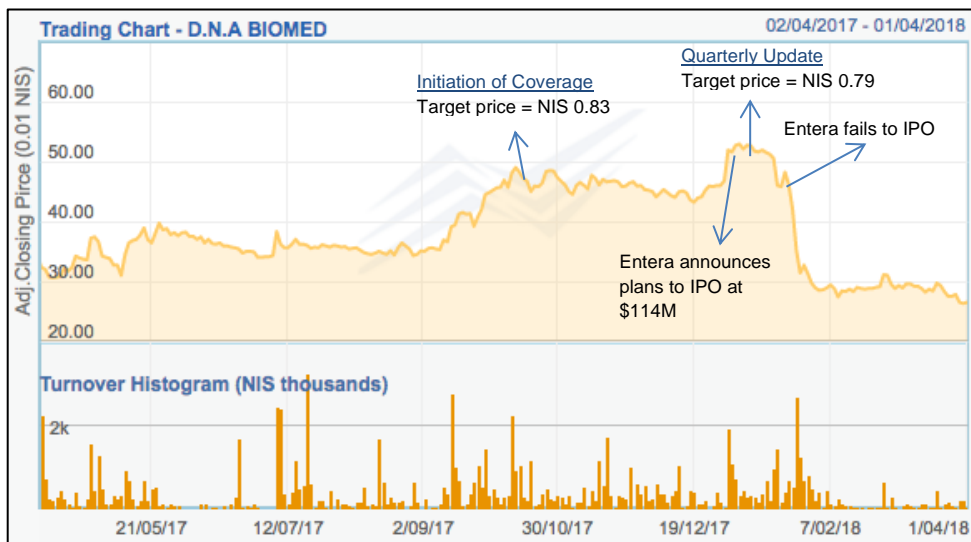
Upcoming Potential Catalysts*

*Should Entera receive FDA approval for the 505(b)(2) regulatory pathway, the milestones below will change

Company	Program	Indication	Event	Significance	Timeline
Entera Bio	EB612: PTH 1-34	Hypoparathyroidism	Initiation of pivotal Phase 2b/3	Medium	2018
			Topline data expected	High	2020
			Expected submission of NDA/BLA to FDA	Medium	2021
			Expected commencement of sales	High	2021/2022
	EB613: PTH 1-34	Osteoporosis	Phase 2a Initiation	Low	2018
			IND submission	Low	2018
			Pivotal phase 2b/3 with strategic partners	High	2019
			Expected commencement of sales by partner	High	2025
	Non-union fractures	Phase 2a Initiation	Low	2018	
BeamMed	-	Osteoporosis	Signing distribution agreements in the United States.	High	2018

Sources: Frost & Sullivan Analysis; DNA Biomedical Solutions Ltd.

Y.T.D. Stock Performance



Appendix I - Financial Reports – DNA Biomedical Solutions Ltd.

Balance Sheet (NIS 000s)	31.12.2016	31.12.2017
Current Assets		
Cash and cash equivalents	934	1,517
Accounts receivable	105	88
Total current assets	1,039	1,605
Non-Current Assets		
Investment in a financial asset at fair value	-	468
Net amount attributable to owners of the company's total assets minus total liabilities per consolidated financial statements, including reputation	-	76,021
Total non-current assets	-	76,489
Total assets	1,039	78,094
Current Liabilities		
Suppliers and service providers	3	13
Other Accounts Payable	342	383
Purchase options in the Company	-	6,050
Put options in the Company	-	2,541
Total current liabilities	345	8,987
Non-Current Liabilities		
Net amount attributable to owners of the company's total assets minus total liabilities per consolidated financial statements, including reputation	83,945	-
Total liabilities	84,290	8,987
Total equity	(83,251)	69,107
Total liabilities and equity	1,039	78,094

*Equity changes are due to capital structure change in 2017

Statement of Profit and Loss (NIS 000s)	2016	2017
General and Administrative Expenses	1,883	2,006
Other Losses	0	18,460
Portion of Profits/Losses shared transaction	148	36,181
Revenue (Loss) from Operations	1,735	56,647

Appendix II - Financial Reports – BeamMed Ltd.

Balance Sheet (\$000s)	2016	2017
Cash and Cash Equivalents	1,716	2,057
Restricted Deposits	165	122
Accts Receivables (Customers)	77	94
Other Receivables	252	148
Inventory	1,044	1,135
Current Assets	3,254	3,556
Intangible Assets	803	610
Deffered Income Taxes	72	65
Fixed Assets	30	23
Non-current Assets	905	698
Total Assets	4,159	4,254
Accounts Payable (Suppliers)	56	136
Other Payables	192	330
Loans from shareholders	387	401
Tax Payable	-	0
Current Liabilities	635	867
Deffered Income Taxes	102	97
Royalties Owned to Government of Israel	49	51
Net Liabilities from employee termination	0	3
Non-current Liabilities	151	151
Total Liabilities	786	1,018
Total Equity	3,373	3,236
Total Liabilities + Equity	4,159	4,254

Statement of Profit and Loss (\$000s)	2016	2017
Sales	3,149	3,372
COGS	1,463	1,574
Net Earnings	1,686	1,798
Marketing and Sales Expenses	629	836
General and Administrative Expenses	821	817
Revenue (Loss) from Operations	236	145
Financing Expenses	(27)	(27)
Financing Income	34	28
Net Financing Expenses/Income	7	1
Profit/Loss before income tax	243	146
Income tax	(30)	(2)
Total Net Annual Profit/Loss	213	144

Appendix III - Financial Reports – Entera Bio Ltd.

<u>Balance Sheet (\$000s)</u>	<u>2016</u>	<u>2017</u>
Cash and Cash Equivalents	4,163	11,746
Restricted Deposits	1,075	0
Other Current Assets	195	671
Current Assets	5,433	12,417
Property and equipment	199	207
Intangible assets	654	654
Non-current Assets	853	861
Total Assets	6,286	13,278
Accounts Payable (Trade)	53	596
Accounts Payable (Other)	604	1,424
Convertible Loans	9,885	0
Total Current Liabilities	10,542	2,020
Convertible Loans	4,835	3,893
Preferred shares	11,031	33,455
Warrants to purchase preferred shares and shares	4,800	5,398
Issuing of preferred shares and warrants	273	0
Net severance pay obligations	51	70
Total non-current Liabilities	20,990	42,816
Total Liabilities	31,532	44,836
Total Capital Deficiency	25,246	31,558
Total Liabilities + Equity	56,778	76,394

<u>Statement of Profit and Loss (\$000s)</u>	<u>2016</u>	<u>2017</u>
Research and Development Expenses	2,648	2,768
General and Administrative Expenses	2,719	8,575
Operating Loss	5,367	11,343
Net Financial Expenses (Income)	(4,168)	(146)
Net Comprehensive Loss	1,199	11,197

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