

Q1 20 Update

June 10, 2020

DNA Biomedical Solutions Ltd.



Company Overview

Israeli holdings firm *DNA Biomedical Solutions Ltd.* (hereinafter 'DNA', 'DNA Biomed' or 'the Company') was founded in 2004 and became public on the Tel Aviv Stock Exchange (TLV: DNA) in 2007. DNA has two key holdings, 26.5% and 43% respective stakes (both fully diluted) in biomedical companies - *Entera Bio* and *BeamMed*.

Entera Bio Ltd. (hereinafter 'Entera' or 'the Company', NASDAQ:ENTX) is a product-focused biotechnology company, founded in 2009 by Dr. Phillip Schwartz. The platform developed by Entera Bio allows for the oral administration of pharmaceutically active large molecules and biologics that would otherwise need to be injected. Entera Bio is conducting clinical trials for two candidate drugs that are designed to treat three different indications: hypoparathyroidism, osteoporosis, and non-union fractures. Entera Bio's proprietary technologies act synergistically to both drive absorption of large molecules via the gastrointestinal tract and protect these same large molecule/biologic drugs from rapid degradation.

BeamMed Ltd. ('BeamMed' or 'the Company') 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.

Entera Bio ([NASDAQ:ENTX](#)), subsidiary of D.N.A, announced, as we expected, on positive interim data from the ongoing Phase 2 clinical trial of EB613 in osteoporosis; Clinical progress is expected to be delayed in a quarter in light of the COVID19 crisis; price target is unchanged

Primary Exchange: TASE

Ticker: TLV: DNA

Sector: Healthcare

Industries: Biotechnology and Medical Devices

Stock Target Price: NIS 2.62

*The target price has changed due to a unification of every 6 ordinary shares into 1 ordinary share.

Data as at June 10, 2020

(Source: TASE)

Closing price: NIS 0.65

52 Week Range: 0.47-1.55

Market cap: NIS 19.6M

of shares: 30.3M

Stock performance (3 mos.): 17%

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Highlights & Analysis

Entera Bio: Entera Bio's platform technology enables oral therapies based on molecules that would otherwise undergo gastric degradation and have limited or no bioavailability. By transforming injectable drugs to oral drugs, the treatment becomes more 'user friendly' which may lead to higher patient and physician acceptance. Furthermore, as an oral drug, various treatment regimens become possible that enable personalized care.

On its first quarter report the company announced the following:

- Entera (EB612): Phase 2b or Phase 3 clinical trial in patients with hypoparathyroidism is planned to 2021.
- Entera (EB613): Entera announced on interim limited biomarker data from the ongoing Phase 2 clinical trial of EB613 in osteoporosis patients. The study demonstrated statistically significant effects on the P1NP biomarker after one month of treatment as compared to placebo, and meaningful increases at months two and three as compared to placebo with the highest EB613 dose (1.5 mg).
- Capital raising : After completion of a private placement of ordinary shares and warrants that raised gross proceeds of \$14.3 million, Entera announced that the company will continue to maintain its financial flexibility by conserving its cash and exploring potential business.

Entera is currently evaluating changes to its operating plan and expects an operating loss of approximately \$10 million for the year ending December 31, 2020 subject to the impact of COVID-19 and the further evaluation of the Phase 2 EB613 results. Financially, we assume Entera will have to raise additional capital by early 2021.

In our view and based on our July [Initiation Report of Entera](#), Entera bio seeks potential partnerships with 1) leading injectable franchises that are now facing a growing threat from biosimilars 2) biologics and proteins that may prove to be complementary to Entera's oral delivery platform, as demonstrated by the strategic research collaboration Entera signed with Amgen in 2018 3) opportunities to license EB613 or EB612 globally, or in certain regions.

The Company expects to file an IND to the FDA in 2020 to support their clinical studies, including the upcoming phase 3 study. We maintain our target price.

Executive Summary

Entera

Entera has witnessed an emerging interest within various healthcare market segments for administration of injectable drug solutions through novel oral means that are considerably more consumer friendly, and consequently more profitable. The medical world has experienced prolific growth in the number of experiments taking place to discover oral solutions to drugs that had only been effective when administered intravenously or intramuscularly. Oral administration has many inherent advantages over injections including self-administration, and suitability for those sensitive to injections. Consequently, the treatment tends to be more receptive among patients. The market potential for orally ingestible alternatives is lucrative. A table of recent activity among leading market players is detailed in the table below.

Investor (Country)	Investee (Country)	Amount	Product	Date
Johnson & Johnson (US)	Protagonist Therapeutics (US)	\$50M	Inflammatory Bowel Disease injectables in pill form	June 2017
Hefei (Sinopharm) (CN)	Oramed (IL)	\$50M	Orally ingestible Insulin	Nov. 2015
Google Ventures, Novartis, AstraZeneca and many others (US)	Rani Therapeutics (US)	\$70M	General platform, including; TNF-alpha inhibitors, interleukin antibodies, insulin and GLP-1	Feb. 2016
25 major financial institutions (US)	Chiasma (US)	\$26.4M (as of August 30, 2017)	Developing and commercializing oral therapies - Phase III clinical trial for the treatment of acromegaly	Via Nasdaq in 2017

Sources: (1) (Business Insider Australia, 2017); (2) (Reuters, 2015); (3) (BioSpace, 2016); (4) (NASDAQ, 2017).

The company's main focus is applying its technology to develop an oral formulation of human parathyroid hormone (1-34), or PTH. PTH has been approved in the U.S. and EU for more than 15 years in injectable form, for the treatment of osteoporosis and currently generated revenue in excess of \$1.6 billion/ year.

PTH is critical in maintaining mineral balance in the body (magnesium, phosphorus and calcium), while its main function is to increase calcium levels when they are too low¹. Their lead oral PTH candidates are EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism (Figure 1). The company has strategically chosen to develop tablets comprising biological substances that today are given as injections, with a proven therapeutic and side effect profile, and are thus well positioned to 'go to market'.

- **EB613 for Osteoporosis:** Entera Bio is set to perform a phase 2a dose ranging study in patients. The company aims to use the 505(b)(2) regulatory pathway, which is less expensive and a much faster route to approval.
- **EB612 for Hypoparathyroidism:** Entera Bio successfully completed a phase 2a clinical trial in Hypoparathyroidism. A pharmacokinetic/pharmacodynamic (PK/PD) cross over study of EB612 versus Natpara (*orphan drug designation*) will be reported later this year with the next planned step for clinical development being a phase 2b/3 pivotal study.

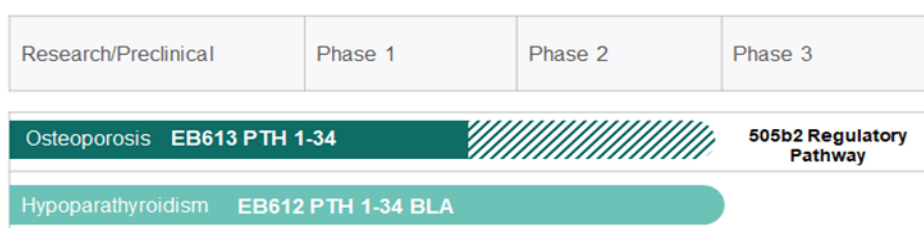
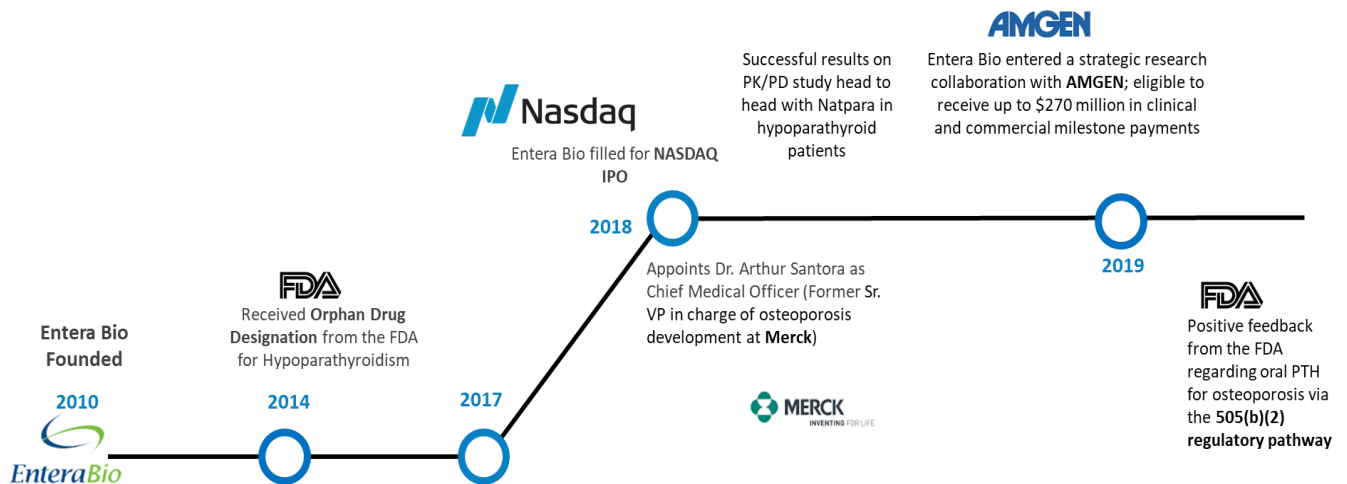


Figure 1: Entera Bio LTD. Lead candidates (Source: Investors presentation 2019)

¹ <https://selfhacked.com/blog/parathyroid-hormone-pt/>



On December 11th 2018, Entera Bio announced a research collaboration and license agreement with Amgen in the area of inflammatory disease and other serious illnesses. Entera will use its proprietary drug delivery platform to develop oral formulations for one preclinical large molecule program that Amgen has already selected. Amgen also has an option to select up to two additional programs to include in the collaboration.² Entera will be eligible to receive up to \$270 million in milestone payments, for the development of three different molecules.

The company received positive feedback from the FDA regarding the use of the 505(b)(2) regulatory pathway to develop their osteoporosis treatment, and additional positive feedback regarding the use of bone mineral density (BMD) rather than fracture incidence as a primary endpoint in their phase 3 clinical trial. This feedback is testimony of the shorter and more efficient development process that the company will need to implement as well as of the market potential.

Entera Bio's clinical development and promising results along with the Amgen agreement emphasize the potential commercial opportunities that exist for the company. Entera's orally delivered PTH hormone may substituted the current injectable hormone, providing a combination of efficacy, tolerability, and convenience. Furthermore, the company could be the first oral bone-building therapy for Osteoporosis and the first to receive orphan designation in both the US & EU for hypoparathyroidism, granting 7 years of market exclusivity. Alongside this, Entera's long-term pipeline is set to develop solutions for indications that presently lack treatment and to license its technology to other companies.

² <https://investors.enterabio.com/news-releases/news-release-details/entera-bio-and-amgen-enter-strategic-research-collaboration>

Entera Bio - Upcoming Potential Catalysts

Program	Indication	Event	Significance	Timeline
EB613: PTH (1-34)	Osteoporosis 505(b)(2)	IND submission	Medium	H1 2020
		Initiation of phase 2a trial- dose ranging study	High	Achieved
		Dose ranging study- bone marker data	High	Mid-2020
		Dose ranging study- bone mineral density (BMD) data	High	H2-2020
		Pivotal phase 3, multicenter study BMD endpoint study comparing Oral PTH with Forteo®	Medium	H1 2021
		Expected commencement of sales by partner	High	H1-2023
EB612: PTH (1-34)	Hypoparathyroidism Orphan Drug	PK/PD study head to head with Natpara in hypoparathyroid patients	Medium	Achieved
		PK/PD study completion	Medium	Achieved
		Submit IND Multi National Study	Medium	H2 2020
		Dose ranging study	Medium	H1-2021
		Phase 2b/3 clinical trial	High	H1-2021
		Expected commencement of sales	High	2023

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

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