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INDEPENDENT EQUITY RESEARCH

Q2-2018 Update Report

5 September, 2018

RedHill announces top-line results from Phase III study of RHB-104 in Crohn's Disease; cash balance improved with $25M (gross) raised at a discount; Top-line results for TALICIA® (RHB-105) - H. pylori infection expected by the end of 2018; target price reduced to NIS 2.23

Primary Exchange: TASE

Secondary exchange: NASDAQ
(ADS/share 1:10)

Ticker: TASE, NASDAQ: RDHL

Sector: Biotechnology

Industry: Drug Development

Data as at 4 September, 2018
(Source: TASE)

Closing price: NIS 2.80

Market cap: NIS 714M

# of shares: 255.1M

Stock performance (12 mos.): -5.7%

Daily-trading-vol. (12 mos.): NIS 997K

Stock target price: NIS 2.23

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Company Overview

RedHill Biopharma Ltd. ("the Company" and/or "RedHill") is an Israeli publically-traded specialty biopharmaceutical company focused on the development and commercialization of late clinical-stage drugs candidates. The Company's main focus is advanced clinical development and commercialization in the US of orally-administered, proprietary, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and cancer.

RedHill is currently promoting three gastrointestinal products and is advancing multiple clinical programs: three Phase III for gastrointestinal and inflammation indications and multiple Phase II for various indications including multiple myeloma, hepatocellular carcinoma, pancreatic cancer, and irritable bowel syndrome with diarrhea.

Highlights & Analysis

In our previous report for Q1-2018 we determined that based on its burn rate, "RedHill will have to raise capital in anticipation of its announcement of top-line Phase III results for Crohn's disease, expected in mid-2018".

- On August 9, 2018 RedHill released a prospectus for $175M in funding (gross).
- On this date, RedHill announced the pricing of an underwritten offering of 4,166,667 American Depositary Shares ("ADSs"), each representing ten of its ordinary shares, at an offering price of $6.00 per ADS, for gross proceeds of approximately $25 million, before commissions and other offering expenses. The offering closed on August 14, 2018, and is expected to fund the company's operations until Q2-2019.

Top-line results from its Phase III study with RHB-104 for Crohn's disease (MAP US study) were released on July 30, 2018; we assume future success in the Phase IIIb clinical trial, but also commercial difficulties down the track.

- Crohn's is a chronic disease that needs to be treated daily. The reduced activity presented in RHB-104 from week 16 and 26 up to week 52 may not be suitable for Crohn's patients.
- Biologic drugs (monoclonal antibodies) present higher remission rates at week 52 than RHB-104. Additionally, biological drugs induce response and remission more rapidly and offers targeted immunosuppression with reduced side effect.
- Data regarding patients completing the trial and dropout rate is not mentioned.
- An open-label extension Phase III study (MAP US2 study) is ongoing to evaluate the safety and efficacy of RHB-104 in subjects who remain with active Crohn's disease (CDAI ≥ 150) after 26 weeks of blinded study therapy in the Phase III MAP US study.

On 30 August 2018 RedHill released its financial report for Q2-2018, detailing the following:

RedHill presented higher net revenues than H1-2017, totaling $4.8M for H1-2018; however, revenues did not meet our expectations.

- Gross profit of $3.1 million in H1-2018, a 10-fold increase on H1-2017.
- Operating loss of $19.6 million in H1-2018, a decrease of 21% on H1-2017.
- Debt-free balance sheet with $28 million in cash at the end of Q2-2018.

We decrease our valuation of the company to $157.5 million (NIS 568M) corresponding to a target price ranging between NIS 2.17 and NIS 2.29; a mean of NIS 2.23 ($6.1 per ADS). Our last target price was NIS 2.59.

- The decrease is mainly attributable to an increase in the number of shares resulting from capital raised at discount.
- We assume future commercial difficulties based on current weak commercial ability with GI sales.
- Numerous current and future treatments for Crohn's disease with higher significant clinical 52 weeks results (see our appendix).
- In our Annual Report for 2017, published 11 March 2018 we raised the target price to 2.59 from the price of 2.27 set in our Q3-2017 report, published 14 December 2017.

Financial Highlights for H1-2018

H1-2018 Financial Results

Net Revenues for the first six-months of 2018 were $4.8 million, an increase on total revenue generated in the corresponding period in 2017. The increase was due to the advancement of promotional activities for Donnatal®, and EnteraGam® and the initial promotion of Esomeprazole Strontium Delayed-Release Capsules

Gross Profit for the first six-months of 2018 was $3.1 million, a 10-fold increase compared to the corresponding period in 2017. The dramatic increase was a result of increased revenues outlined above.

Research and Development Expenses for the first six-months of 2018 totaled $12.5 million, a decrease of 33% from the corresponding period in 2017. This can be attributed to substantial investment in the Phase III trial for Crohn's disease made in H1-2017.

Selling, Marketing and Business Development Expenses for the first six-months of 2018 totaled $6.3 million, an increase of 37% from the corresponding period in 2017. The increase can be attributed to the company's substantial marketing activity in the lead up to the release of top-line data for the first part of its Phase III trial in Crohn's disease. It can be expected that similar activity will take place in H2-2018 in the wake of Top-line results for TALICIA® (RHB-105) - H. pylori infection, expected before year's end.

General and Administrative Expenses for the first six-months of 2018 totaled $3.9 million, an increase of 21% compared to the corresponding period in 2017. RedHill did not detail reasons for this increase in its financial statements, which is rather unexpected for an increase of such magnitude.

Operating Loss for the first six-months of 2018 totaled $19.6 million, a decrease of 21% compared to the corresponding period in 2017. The decrease a result of substantially reduced R&D expenses and a 10-fold increase in gross profit though was partially offset by significant increases in S&M and G&A expenses.

Net Cash Used in Operating Activities for the first six-months of 2018 totaled $17.9 million, compared to $20.0 for the corresponding period in 2017. The decrease is a result of substantial investment in the Phase III trial for Crohn's disease made in H1-2017.

Cash Balance as of 30 June, 2018 was $28.0 million. Together with the $25M gross capital raised in August, the company has sufficient cash to fund its operations until Q2-2019, during which it will need additional capital. The prospectus released by the company for gross capital raising of $175M in July 2018 still allows for another $150M in gross capital raising. Should this total sum be raised by Q1-2019. The company will have sufficient cash to run its operations until Q3-2020, by which time it is expected that the majority of its assets currently undergoing clinical trials will either already be commercialized, or on the verge of commercialization.

Capital Raising

In our previous report for Q1-2018 we determined that based on its burn rate, "RedHill will have to raise capital in anticipation of its announcement of top-line Phase III results for Crohn's disease, expected in mid-2018".

On July 23 RedHill released a draft prospectus for $175M in funding (gross). On August 9, 2018 RedHill released a full prospectus for a round of capital raising consisting of two parts. Part (a) will see 29,630,235 Ordinary Shares issuable upon the exercise of outstanding options to purchase the same number of shares at a weighted average exercise price of $1.03 (NIS 3.80) - equivalent to 2,963,023 ADSs at $10.30 per ADS. Part (b) involves the sale of 2,025,458 ADSs representing 20,254,580 ordinary shares already issued in March 2016, which remain unsold. These are being offered at an exercise price of $1.333 (NIS 4.90) per share or $13.33 per ADS). RedHill will pay up to 8% of the capital raised in fees and commissions to underwriters and other service providers.

On August 9, RedHill announced the pricing of an underwritten offering of 4,166,667 American Depositary Shares ("ADSs"), each representing ten of its ordinary shares, at an offering price of $6.00 per ADS, for gross proceeds of approximately $25 million, before commissions and other offering expenses. The trading price of RDHL ADSs at the time of the underwritten offering pricing announcement was $6.55. **It can be concluded that RedHill raised capital at a discount of 9.2%, as per the trading price on August 9.** The offering closed on August 14, 2018 and is expected to fund the company's operations until Q3-2019.

Clinical Highlights

RHB-104 is a combination therapy for Crohn's disease. The drug combines three well studied antibiotics (Clarithromycin, Clofazimine and Rifabutin) that have anti-bacterial and anti-inflammatory activities. The first phase III clinical trial (MAP US) assessed the Efficacy and Safety of Fixed-dose Combination of RHB-104; the clinical trial's results were published on 30 July, 2018. The extension study (MAP US II) is still enrolling (testing the effect of RHB-104 on patients that still have active crohn's disease in week 26).

TALICIA® (RHB-105) - H. pylori infection (confirmatory Phase III) (FDA Fast-Track QIDP status). In June 2018 Redhill enrolled the 400th patient (of the planned total of 444) for its confirmatory Phase III study with TALICIA® (RHB-105) for H. pylori infection (ERADICATE Hp2). RedHill expects to complete enrollment of the ERADICATE Hp2 study in the third quarter of 2018 and announce top-line results in Q4-2018. Subject to a successful outcome and additional regulatory feedback, the ERADICATE Hp2 study is expected to complete the package required for a potential U.S. NDA for TALICIA®. The filing is planned for early 2019 and, if accepted for review, the FDA could potentially approve TALICIA® in the second half of 2019 following a priority NDA review.

BEKINDA® (RHB-102) 12 mg - IBS-D (Phase II) On January 16, 2018, RedHill announced positive final results from the Phase II study with BEKINDA® 12mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). The randomized, double-blind, placebo-controlled Phase II study successfully met its primary endpoint, improving stool consistency (per FDA guidance definition) by an absolute difference of 20.7% vs. placebo (p-value=0.036). RedHill plans to meet with the FDA in the third quarter of 2018 to discuss the design for one or two pivotal Phase III studies.

RHB-102, 24mg positive results from Phase III clinical study in the U.S for patients suffering from acute gastroenteritis (the GUARD study). The study successfully met its primary endpoint of efficacy in treatment of acute gastroenteritis and was found to be safe and well tolerated in this indication.

YELIVA® (ABC294640) – **Cholangiocarcinoma** (bile duct cancer); (Phase IIa, ABC-108), FDA Orphan Drug designation. The company is still enrolling patients for its single-arm Phase IIa study with YELIVA® (ABC294640), for Patients with advanced, unresectable intra-hepatic and extra-hepatic cholangiocarcinoma. Enrollment is expected to be completed by the end of 2018. The study is being conducted at major Mayo Clinic campuses in Arizona and Minnesota, University of Texas MD Anderson Cancer Center and the Huntsman Cancer Institute, University of Utah Health. The trial is designed to enroll up to 39 patients.

RHB-106 – Encapsulated formulation intended for the preparation and cleansing of the gastrointestinal tract prior to the performance of abdominal procedures that was licensed to Salix Pharmaceuticals. RedHill recently amended its 2014 worldwide license agreement with Salix Pharmaceuticals related to RHB-106 encapsulated bowel cleanser, as well as additional related rights. The amendment clarifies the development efforts to be used by Salix, as well as providing for enhanced involvement by RedHill in certain intellectual property matters.

RHB-204 - nontuberculous mycobacteria (NTM) infections (planned pivotal Phase III) (FDA Fast-Track QIDP status). A pivotal Phase III study with RHB-204 for the treatment of nontuberculous mycobacteria (NTM) infections is expected to be initiated in the second half of 2018, subject to regulatory approvals. RedHill plans to assess RHB-204 as a first-line treatment of NTM disease caused by mycobacterium avium complex (MAC) infection.

RHB-107- pancreatic cancer, is a proprietary, first-in-class, orally-administered potent urokinase-type plasminogen activator (uPA), presenting a new non-cytotoxic approach to cancer therapy, as well as other indications such as inflammatory digestive diseases and inflammatory lung diseases. RedHill acquired the worldwide exclusive development and commercialization rights to RHB-107 (excluding in Greater China) for all indications from Munich-based WILEX AG in June 2014. RHB-107 has undergone several Phase I studies and two Phase II clinical studies,

including a Phase II proof of concept study in locally advanced non-metastatic pancreatic cancer, demonstrating safety and tolerability. RHB-107 was granted FDA Orphan Drug designation for the adjuvant treatment of pancreatic cancer.

RHB-104 - Crohn's disease (MAP US clinical trial)

Crohn's disease is a chronic inflammatory disease of the gastrointestinal tract. Genetic, environmental, immunological and bacterial factors are all thought to contribute to the disease. Thus, effective therapeutic approaches are of high clinical relevance in patients with Crohn's. Current treatment and development are emerging in order to prevent the disease's progression and promoting remission.

On the 30th of July RedHill published positive results for its phase III clinical trial, MAP US, which aimed in investigating the ability of RHB-104 to induce remission in Crohn's disease patients at week 26. RHB-104 is a combination therapy of three well studied antibiotics targeting the hypothesis that Crohn's disease is caused by *Mycobacterium avium paratuberculosis* (MAP) infection in susceptible patients. Several days after the first announcement, RedHill published a report that elaborates on their phase III results and compares their results to the current available treatments.

The published results were as follows:

- RHB-104 met the primary endpoint of the trial by achieving remission (CDAI <150) by week **26** (37% vs. 23% placebo, p=0.013).
- RHB-104 patients had a statistically significant greater response at week 26 (defined as a decrease ≥100 in CDAI from the baseline) compared to placebo (44% vs. 31% placebo, p= 0.028).
- RHB-104 patients demonstrated statistically significant early remission rates. By week **16** (42% vs. 29% placebo, p= 0.019).
- RHB-104 patients demonstrated statistically significant durable remission over weeks 16-52, defined as continuous remission throughout the period, (18% vs. 9% placebo, p= 0.038).
- At 52 weeks of treatment, remission in RHB-104 continued to be favorable to placebo (27% vs. 20% placebo, p= 0.155)
- An analysis of maintenance of remission at week 52 in subjects noted to be in remission at week 16 also demonstrated statistically significant benefit with RHB-104 over placebo (25% vs. 12%, p= 0.007).

Analysis of Trial Results

Biologic drugs and antibiotics are different in terms of mechanism of action; the first acts on inflammatory related cascades while the later on direct killing of bacteria. Loss or reduced activity of each one has a completely different meaning in terms of stability, compliance and potential therapeutics. The pathophysiology of Crohn's disease is not completely understood despite recent developments, thus ideally for clinician is to select the best agent for individual patients.

The MAP US clinical trial tested the effect of RHB-104 on CD patients with moderate to severe disease. The primary endpoint was remission at week 26 and reduction of the total Crohn's Disease Activity Index (CDAI) score to less than 150. The company achieved remission (CDAI <150) by week 26 (37% vs. 23% placebo, p=0.013). The remission was noticed also earlier, by week 16 (42% vs. 29% placebo, p= 0.019). The patients were significantly responsive to the treatment on week 26 (decrease ≥100 in CDAI from the baseline) (44% vs. 31% placebo, p= 0.028).

Crohn is a chronic disease that needs to be treated daily. Once analyzing the results, there is clearly a reduced activity from week 16 (42%) and 26 (37%) to week 52, thus it is not considered an adequate treatment for all Crohn's patients. In light of these results, RHB-104 durability issue should be addressed. Furthermore, information regarding the patients that completed the trial and the dropout rate should be mentioned.

The company is currently enrolling patients for a trial investigating the effect of continuing treatment with RHB-104 from week 26.

RedHill will engage in a confirmatory phase III trial based on FDA requirements. These clinical studies will be expensive and prolonged (3-4 years). Although their published clarification, the company needs to address some important issues from activity of the drug, durability, resistance and prolong activity.

Appendix 2 summarizes the most frequently used biological drugs for Crohn's treatment and their clinical trials. For example, Vedolizumab (GIMINI 2 trial), an open label. The drug was continually taken every 6 and 8 weeks, the patients retained their clinical remission at week 52 (36-39% Vs 21.6 in the placebo group). Other Biologic drugs (such as Stelara and Risankizumab) have remission rates of ~50% at week 52.

Financial Analysis

Revenues

In our most recent coverage we outlined that our data (based on the 'Orange book' which contains all drugs sales data) indicates, for example, that before Redhill was granted the rights for distribution of Donnatel, worldwide sales of this drug were $142M in 2015 and $139M in 2016, the majority of sales being in the US. We also estimated, based on the same source, sales for the other two GI products for the upcoming years. Given that the company doesn't share any relevant data with regard to its sales (for example, revenue sharing agreements, total gross sales), we assumed a 5% revenue share based on our assumptions, and the US share of the global market.

This led us to forecast RedHill's net revenues for 2018 at approximately $15.9M or approx. $4.0M per quarter. RedHill's sales of its GI drugs totaled $2.4 million and $2.35 million for Q1-2018 and Q2-2018 respectively.

We assume, RedHill's revenue for H1-2018 totals only 60% of its potential based upon total market sales in 2015 and 2016. Therefore, these results can be considered a short fall of approx. 40% as we have conservatively estimated a 5% revenue share and not taken into account any market growth/decline since 2016.

On a positive note, we addressed RedHill's new strategy in forming a sales force in the US in our initiation report of 12 July 2017. After years of successfully implementing a "standard" drug development strategy, with a business model based on licensing out its IP, the company has decided to expand its strategy and set up a sales organization in the US that will drive revenues from selling drugs.

Financially, RedHill maintains a debt-free balance sheet with $28 million in cash at 30 June 2018. Given the $25M gross capital raising announced in August 2018, and based on the company's current net burn rate, **RedHill needs to raise capital before Q2-2019 in order to sustain its current levels of expenditure.** To this effect RedHill released a prospectus for $175M in gross capital in July 2018. Net of the $25M raised in August, should RedHill raise an additional $150M by Q1-2019 the company will have sufficient cash to FUND its operations until Q3-2020, by which time it is expected that the majority of its assets currently undergoing clinical trials will either already be commercialized, or on the verge of commercialization.

We evaluate the company's equity value at $157.5 million (NIS 568.4M) corresponding to a target price ranging between NIS 2.17 and NIS 2.29; a mean of NIS 2.23 ($6.1 per 1 ADS).

Upcoming Potential Catalysts

Program	Event	Significance	Timeline	Update
BEKINDA® - RHB-102 (gastroenteritis & IBS-D)	Top-line Phase II results (IBS-D)	Medium	**Sep 2017**	**Achieved**
	Top-line Phase III results (gastroenteritis)	Medium	**Mid-2017**	**Achieved**
	Clinical Study Report (CSR) from the successful Phase III study (gastroenteritis)	Medium	**Q3-2017**	**Achieved**
RHB-103 - RIZAPORT® (Migraine)	U.S. NDA re-submission	Low	**Oct 2017**	**Achieved**
RHB-104 (Crohn's Disease)	Meeting with Data and Safety Monitoring Board Group for the MAP U.S. Phase III study for Crohn's disease including safety and interim efficacy analysis, with evaluation of option of early stop for success for overwhelming efficacy.	High	**Mid-2017**	**Achieved**
	Top-line results MAP US Phase III	High	**Mid-2018**	**Achieved**
TALICIA™ (RHB-105) (*H. pylori*)	Initiation of a confirmatory Phase III study for treatment of *H. pylori* infection	Medium	**Mid-2017**	**Achieved**
	Top-line Phase III results	High	**Q4-2018**	On track

YELIVA®	Completion of enrolment for a Phase IIa study with YELIVA® for ulcerative colitis	Low	**Q4-2018**	On track
RHB-204 for nontuberculous mycobacteria (NTM) infections	Initiation of pivotal Phase III study (FDA Fast-Track QIDP status)	Medium	**Q1-2019**	On track

Sources: Frost & Sullivan Analysis; RedHill.

12 months Stock Movement for TASE:RDHL

Source: Tel Aviv Stock Exchange

Appendix I - Financial Reports for H1-2018

Balance Sheet (US$000s)	March 31, 2018	June 30, 2018
Cash and cash equivalents	7,560	5,564
Bank deposits	13,206	8,225
Financial assets at fair value through profit or loss	15,584	14,113
Trade receivables	1,809	1,796
Prepaid expenses and other receivables	2,019	1,831
Inventory	560	690
Total Current Assets	**40,738**	**32,219**
Bank deposits	150	144
Fixed assets	221	200
Intangible assets	5,285	5,285
Total Non-Current Assets	**5,656**	**5,629**
Total Assets	**46,394**	**37,848**
Accounts payable	2,724	4,023
Accrued expenses and other current liabilities	6,481	5,354
Payable in respect of intangible asset purchase	500	500
Total Current Liabilities	**9,705**	**9,877**
Total Non-Current Liabilities: Derivative Financial Instruments	**398**	**2,065**
Total Equity	**36,291**	**25,906**
Total Liabilities and Equity	**46,394**	**37,848**

Consolidated Statement of Profit and Loss (US$000s)	June 30, 2017	June 30, 2018
Net Revenues	483	4,795
Cost of Revenues	272	1655
Gross Profit	**211**	**3,140**
Research and Development Expenses, Net	8,434	12,460
Selling, Marketing and Business Development Expenses	3,376	6,293
General and Administrative Expenses	1,940	3,939
Operating Loss	**13,539**	**19,552**
Financial Income Net	2,516	(1,501)
Loss and Comprehensive Loss for the Period	**11,023**	**21,053**
Loss per ordinary share, basic and diluted (USD)	0.06	0.11

Appendix II - Current Treatments for Crohn's

Vedolizumab (Entyvio®)- GEMINI2 and GEMINI3

GEMINI2:

- At week 6, 14.5% of patients receiving the drug in Cohort 1 (placebo/drug) and 6.8% of the placebo group had achieved remission (CDAI≤150), p=0.02.
- Patients in Cohort 1 and Cohort 2 (drug-open label) who responded to induction therapy 39.0% (every 8 weeks) and 36.4% (every 4 weeks) were in clinical remission at week 52, compared to placebo (21.6%)**.**

GEMINI3:

- The proportion of patients in clinical remission **at week 6** for the TNF antagonist–failure population - **no statistically** significant difference was observed between the vedolizumab (15.2%) and placebo (12.1%) groups.
- In the TNF antagonist–failure population, greater proportions of vedolizumab-treated patients than placebo-treated patients were in clinical remission at **week 10** (vedolizumab, 26.6%; placebo, 12.1%).
- Greater proportions of vedolizumab-treated patients also had a CDAI-100 response at **week 6** (vedolizumab 39.2%; placebo 22.3%) and at **week 10** (vedolizumab, 46.8%; placebo, 24.8%).
- In the **overall population** (previously treated with TNF alpha antagonist and naïve population), a greater proportion of vedolizumab-treated patients (19.1%) than placebo-treated patients (12.1%) were in clinical remission at **week 6**.
- Exploratory analyses in the overall population showed that the proportion of patients with a **CDAI-100** response was greater with vedolizumab at **week 6** (vedolizumab, 39.2%; placebo, 22.7%) and at **week 10** (vedolizumab, 47.8%; placebo, 24.2%).
- Naive subgroup- clinical remission at **week 6** (vedolizumab, 31.4%; placebo, 12.0%); remission at **week 10** (vedolizumab, 35.3%; placebo, 16.0%); CDAI-100 response at **week 6** (vedolizumab, 39.2%; placebo, 24.0%); and CDAI-100 response at **week 10** (vedolizumab, 51.0%; placebo, 22.0%)
    - Collectively, the primary and secondary outcome results suggest that in patients with CD and previous TNF antagonist failure, effects of vedolizumab on clinical remission may not become evident until between weeks 6 and 10.

Adalimumab (Humira ®)-GAIN, CLASSIC I and CHARM.

GAIN study-

- At week 4, 21% of patients in the adalimumab group compared with 7% of patients in the placebo group achieved remission.
- The difference between the adalimumab and placebo groups was evident at **week 1** for a decrease of 70 points or more in the CDAI score, the more sensitive measure of response. The rates of 70 and 100 point response were greater in the adalimumab group than in the placebo group at weeks 1, 2 and 4 as can be seen in the Table below.

	70 point response		100 point response	
	Adalimumab	Placebo	Adalimumab	Placebo
Week 1	35%	21%	20%	12%
Week 2	52%	33%	37%	18%
Week 3	52%	34%	38%	25%

CHARM study-

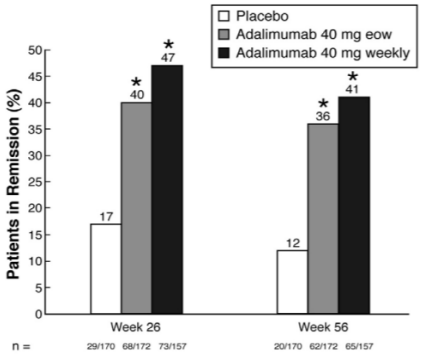
The primary objective of the study was to assess the benefit of two adalimumab dosing regimens in **maintaining clinical remission at 26 and 56 weeks** in patients who had an initial response to two adalimumab injections of 80 mg at week 0 and 40 mg at week 2.

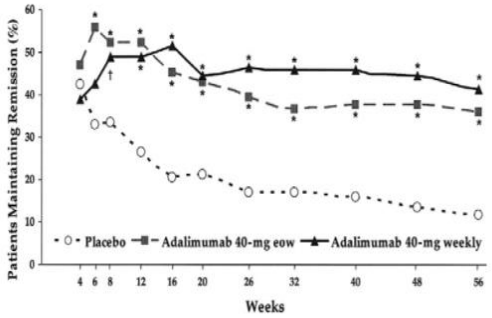
Results:

- Responders in remission (CDAI score 150) at week 26: adalimumab 40-mg every other week **40%,** adalimumab 40 mg weekly **47%**, and placebo 17%
- Responders in remission (CDAI score 150) at week 56 : adalimumab 40 mg every other week **36%**, adalimumab 40 mg weekly **41%**, and placebo 12%

The figure below depicts clinical remission and the maintenance of remission at weeks 26 and 56.

It is evident that the response to the drug is dose dependent.





- Adalimumab maintained significantly greater rates of response (CDAI score decreased from baseline of 70 and 100) at both weeks 26 and 56 as seen in the table below.

Patients With a Decrease From Baseline in CDAI Score ≥100 and ≥70

	Treatment group[a]		
Clinical response	Placebo (n = 170)	Adalimumab every other week (n = 172)	Adalimumab weekly (n = 157)
Decrease from baseline ≥100			
Week 26	45 (26.5)	89 (51.7)	82 (52.2)
Week 56	28 (16.5)	71 (41.3)	75 (47.8)
Decrease from baseline ≥70			
Week 26	48 (28.2)	93 (54.1)	88 (56.1)
Week 56	30 (17.6)	74 (43.0)	77 (49.0)

NOTE. All values are expressed as n (%). $P < .001$ for pairwise comparisons of each active treatment group vs placebo at all end points.
[a]Randomized responders.

CLASSIC I

- For the primary analysis at week 4, there was a significant difference in the remission rates between the adalimumab 80 mg/40 mg (24%), adalimumab 160 mg/80 mg (36%), and placebo (12%) groups.
- There was a linear dose response across the 3 adalimumab treatment groups at week 4 for the endpoints of remission and 100-point response, with the highest dose group demonstrating statistical significance in the pairwise comparisons with placebo.

Ustekinumab (STELARA®) - UNITI-1 (CD-1), UNITI-2 (CD-2) and IM-UNTI (CD-3).

Induction of Clinical Response and Remission in CD-1* and CD-2**						
	CD-1 n=741			CD-2 n=627		
	Placebo N=247	STELARA®† N=249	Treatment difference and 95% CI	Placebo N=209	STELARA®† N=209	Treatment difference and 95% CI
Clinical Response (100 point), Week 6	53 (21%)	84 (34%)[a]	12% (4%, 20%)	60 (29%)	116 (56%)[b]	27% (18%, 36%)
Clinical Remission, Week 8	18 (7%)	52 (21%)[b]	14% (8%, 20%)	41 (20%)	84 (40%)[b]	21% (12%, 29%)
Clinical Response (100 point), Week 8	50 (20%)	94 (38%)[b]	18% (10%, 25%)	67 (32%)	121 (58%)[b]	26% (17%, 35%)
70 Point Response, Week 6	75 (30%)	109 (44%)[a]	13% (5%, 22%)	81 (39%)	135 (65%)[b]	26% (17%, 35%)
70 Point Response, Week 3	67 (27%)	101 (41%)[a]	13% (5%, 22%)	66 (32%)	106 (51%)[b]	19% (10%, 28%)

Study **IM-UNTI** (CD-3) - The maintenance study evaluated 388 patients who achieved clinical response (≥100 point reduction in CDAI score) at Week 8 of induction with STELARA® in studies CD-1 or CD-2.

Patients were randomized to receive a subcutaneous maintenance regimen of either 90 mg STELARA® every 8 weeks or placebo for 44 weeks:

Clinical Response and Remission in CD-3 (Week 44; 52 weeks from initiation of the induction dose)			
	Placebo* N=131†	90 mg STELARA® every 8 weeks N=128†	Treatment difference and 95% CI
Clinical Remission	47 (36%)	68 (53%)[a]	17% (5%, 29%)
Clinical Response	58 (44%)	76 (59%)[b]	15% (3%, 27%)
Clinical Remission in patients in remission at the start of maintenance therapy**	36/79 (46%)	52/78 (67%)[a]	21% (6%, 36%)

- At Week 44, 47% of patients who received STELARA® were corticosteroid-free and in clinical remission, compared to 30% of patients in the placebo group.

Disclaimers, disclosures, and insights for more responsible investment decisions

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Credit to Experts: Dr. Tiran Rothman; Daniel Grunstein; Dr. Hadar Cohen-Halevy

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