Biotechnology

RCPI - OTC May 17, 2016

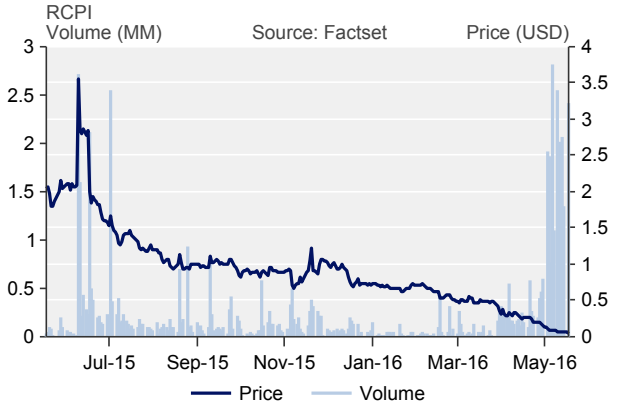
Closing Price 05/16/2016	**$0.04**
Rating:	Buy
12-Month Target Price:	$4.00
52-Week Range:	$0.04 - $3.65
Market Cap (M):	1
Shares O/S (M):	15.0
Float:	95.2%
Avg. Daily Volume (000):	455
Dividend:	$0.00
Dividend Yield:	0.00%
Risk Profile:	Speculative
Fiscal Year End:	December

Total Expenses ('000)

	2016E	2017E	2018E
1Q	1,361A	2,899	3,591
2Q	1,750	2,969	3,691
3Q	2,475	3,109	3,891
4Q	2,600	3,179	3,991
FY	13,186	12,154	15,164
Prior	14,007	16,187	19,205

GAAP EPS

	2016E	2017E	2018E
1Q	(0.22)A	(0.09)	(0.10)
2Q	(0.08)	(0.09)	(0.10)
3Q	(0.08)	(0.10)	(0.11)
4Q	(0.08)	(0.10)	(0.11)
FY	(0.54)	(0.37)	(0.41)
Prior	(0.57)	(0.59)	(0.60)



Rock Creek Pharmaceuticals — Buy

Anatabine Citrate: On the Path to Regulatory Approval

Summary

- **Rock Creek reported 1Q16 with a net loss of $2.7M or $(0.22) per share.**
- **Anatabine citrate, which is a synthetic derivative of the anti-inflammatory compound, anatabine (from the tobacco plant), is in clinical development for the treatment of psoriasis. Anatabine was a successful nutraceutical ("Anatabloc") used by more than 500,000 people to alleviate inflammation conditions, demonstrating proof of concept. Given the popularity of the product and input from the FDA, Rock Creek voluntarily moved anatabine citrate to development stage to investigate clinical benefits.**
- **A phase I safety study for an oral formulation has already been completed and Rock Creek has demonstrated in cell lines slowing down regulation of two key mediators of inflammation (STAT-3 and NF-κB). Hitting both STAT-3 and NF-κB is what differentiates anatabine citrate from other compounds.**
- **The target now is demonstrating proof of concept in patients with mild to moderate psoriasis. A phase Ib study is expected to be designed and completed in 2016. Pending positive data a phase IIa/II should follow in 2017.**
- **The company is also developing topical formulations which have recently demonstrated positive preclinical data in models of psoriasis (see pages 2-5). Anatabine citrate, applied topically, reduced the proliferation of keratinocytes (skin cells) with concomitant knockdown of STAT-3 and NF-κB expression. Rock Creek plans to submit the data for publication and use the data, in part, for the design of the phase Ib study.**
- **Conclusion. Rock Creek is now a clinical-stage pharmaceutical company and with proof of principle in hand as well as anecdotal POC data from 1000's of patients, is on the path towards regulatory approval.**

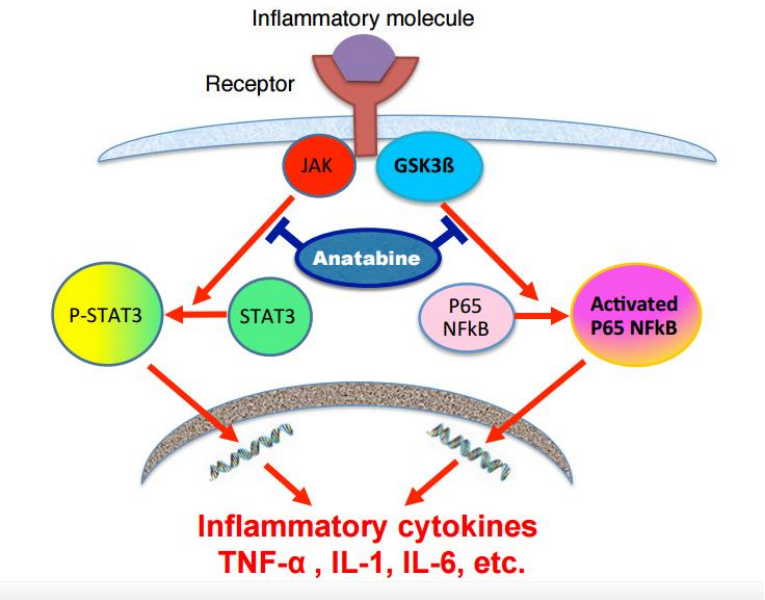
Details

Phase I PK Assays: Blood samples from patients were taken before and after anatabine citrate was given. Each sample was exposed to bacterial antigen called LPS (bacterial lipopolysaccharide). When blood is exposed to LPS, the white blood cells ramp up the inflammatory response, which is driven by increased expression of STAT-3 and NF-κB. Samples taken before patients were exposed to anatabine citrate were stimulated with LPS and the fold-increase in STAT-3 and NF-κB was used to establish the reference point(s). Blood samples taken after anatabine citrate was administered were then stimulated with LPS and the changes in STAT-3 and NF-κB expression were then compared to the reference points. STAT-3 expression was knocked down more than NF-κB. However, it was noticed that the 'before' STAT-3 increased a lot more than the 'before' NF-κB after the two hour LPS exposure. Thus the impact of anatabine citrate appears greater on STAT-3. It's possible the reference NF-κB peaked much earlier than 2 hours and it was 'missed'. Rock Creek is evaluating the assays and may need to run them individually and at different reference point times.

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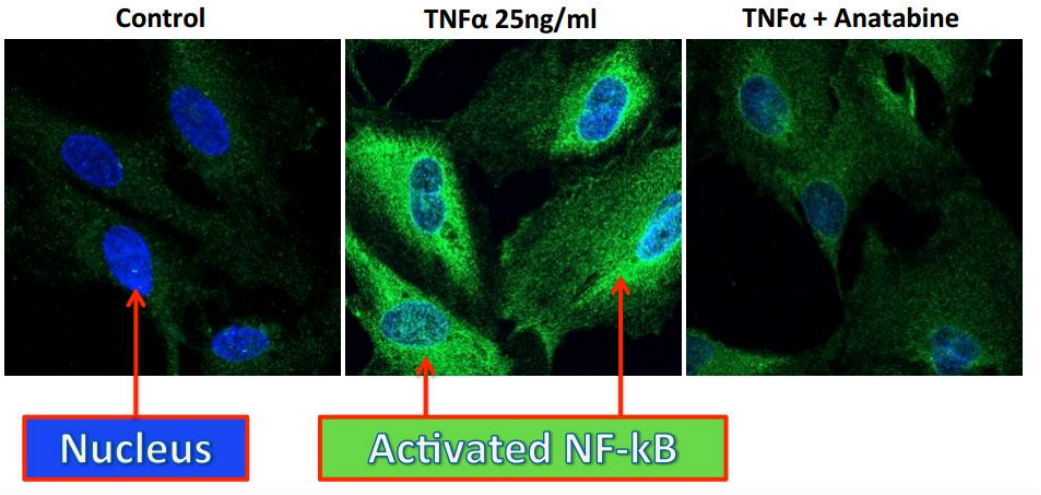
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Exhibit 1. Anatabine Citrate mechanism of action. Inflammatory molecules that bind to cell surface receptors can drive two pathways that ultimately lead to the expression of pro-inflammatory genes. The two pathways are regulated by the transcription factors NF- κB (nuclear factor kappa-light-chain enhancer of activated B cells) and STAT3 (signal transducer and activator of transcription 3). Many anti-inflammatory therapeutics target either NF- κB or STAT3, but not both, allowing the cell to have a redundant escape pathway to drive inflammation. Anatabine citrate's unique MOA targets both pathways.



Source: Rock Creek Pharmaceuticals presentation

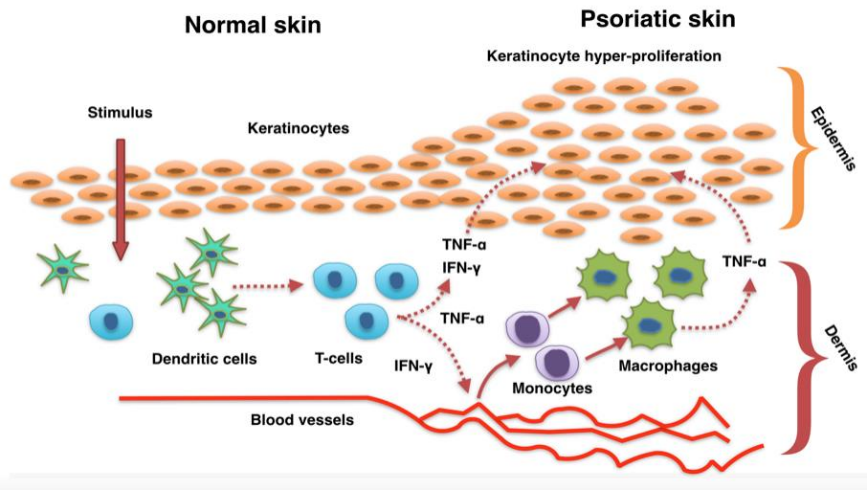
Exhibit 2. Anatabine citrate inhibits NFK-B. Shown below are microglia cells treated with the inflammatory cytokine TNF-alpha. In the middle panel untreated cells express an abundance of activated NF- κB where as in the right panel, cells treated with anatabine citrate have reduced NF-B κ expression after only 15 minutes.



Source: Rock Creek Pharmaceuticals presentation

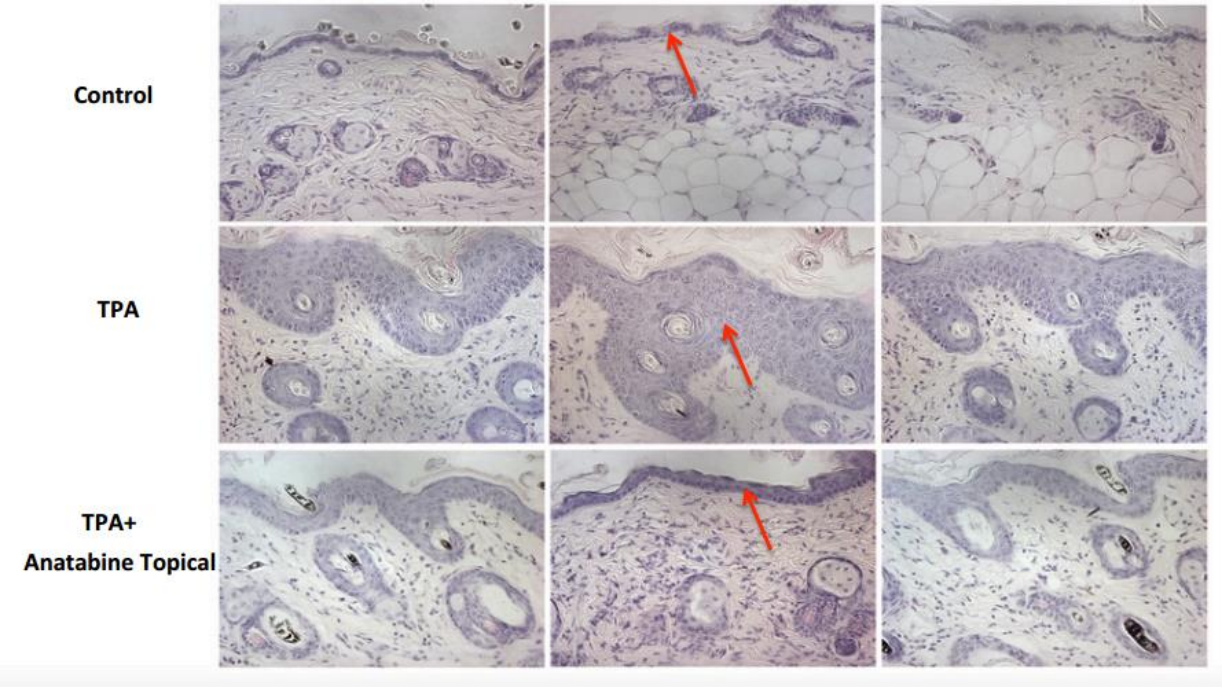
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Exhibit 3. Targeting psoriasis. Hyper-inflammation in the subdermal layers of skin driven by the presence of activated macrophages, monocytes and T cells drives the proliferation of keratinocytes, a hallmark of psoriatic lesions.



Source: Rock Creek Pharmaceuticals presentation

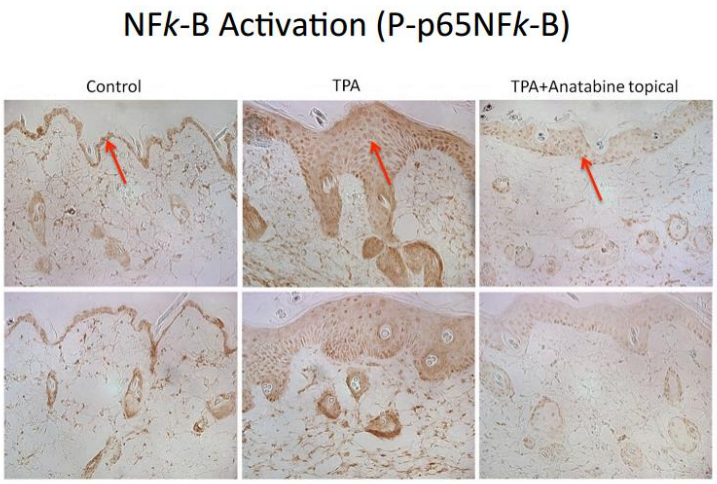
Exhibit 4. Resolution of psoriatic plaques following anatabine citrate treatment. TPA (12-O-tetradecanoyl phorbol-13-acetate) treated rodents (induces psoriatic plaques) treated with anatabine citrate demonstrated reduction in keratinocyte proliferation.



Source: Rock Creek Pharmaceuticals presentation

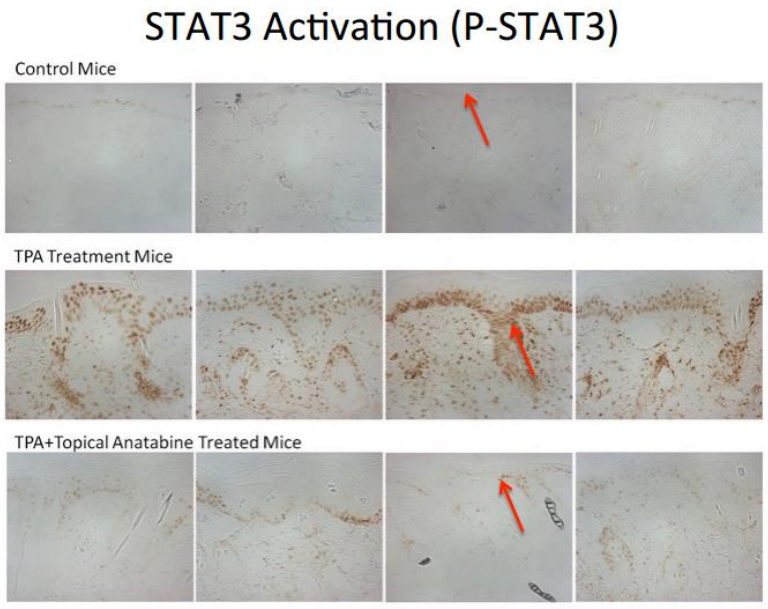
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Exhibit 5. Anatabine citrate reduces NF- κB expression in TPA-induced psoriatic plaques. In the same study presented in exhibit 4, mice with TPA-induced plaques treated with anatabine citrate show a reduction in NF- κB activation.



Source: Rock Creek Pharmaceuticals presentation

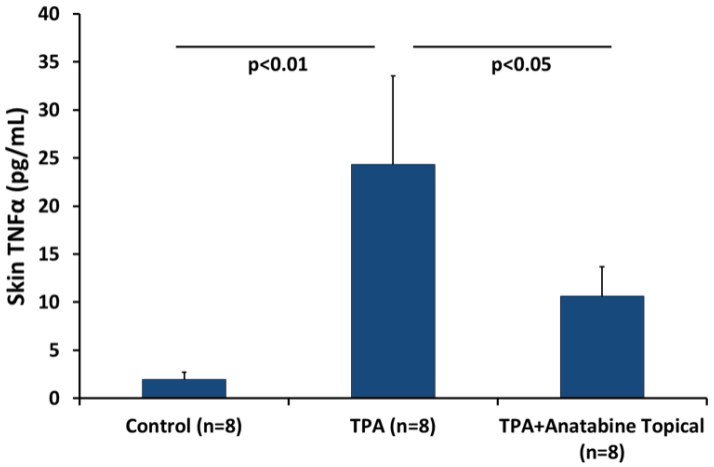
Exhibit 6. Anatabine citrate reduces STAT3 expression in TPA-induced psoriatic plaques. In the same study presented in exhibit 4, mice with TPA-induced plaques treated with anatabine citrate show a reduction in STAT3 activation.



Source: Rock Creek Pharmaceuticals presentation

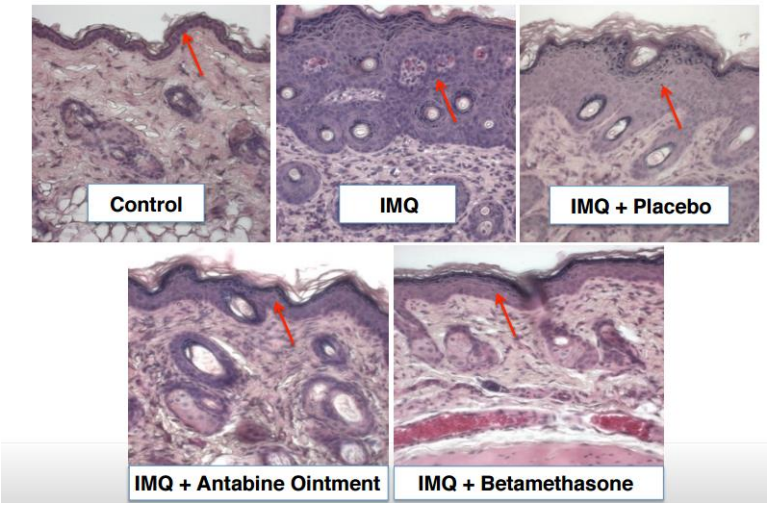
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Exhibit 7. Anatabine citrate reduces levels of the inflammatory cytokine TNF-alpha in TPA-induced psoriatic plaques.



Source: Rock Creek Pharmaceuticals presentation

Exhibit 8. A second psoriasis model demonstrates similar efficacy for anatabine citrate. Rock Creek initiated a second preclinical study of psoriasis using the imiquimod (IMQ)-induced psoriasis mouse model. This model recapitulates many features of the pathology of human psoriasis such as erythema, scaling, keratinocyte proliferation, skin thickening and activation of IL23, IL17 and IL22 cytokines. Shown below are sections of skin demonstrating a reduction in keratinocyte proliferation in rodents treated with anatabine citrate.



Source: Rock Creek Pharmaceuticals presentation

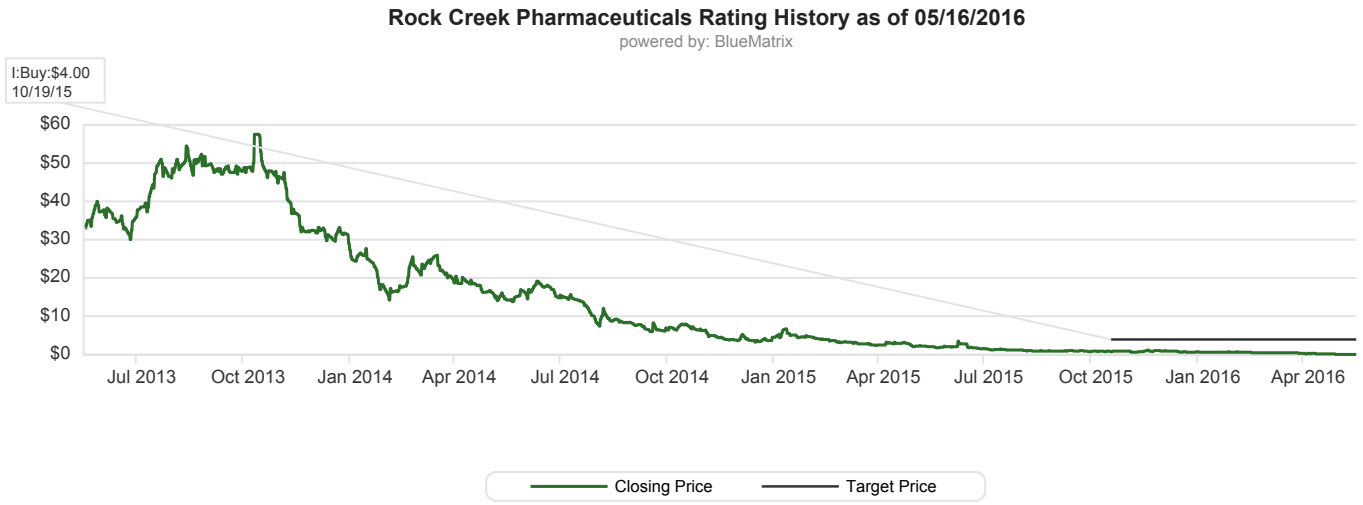
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Rock Creek Pharmaceuticals.: Income Statement ($000)															
RCPI: YE December 31	**2015A**	**1Q16A**	**2Q16E**	**3Q16E**	**4Q16E**	**2016E**	**2017E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**
Product sales															
Anatabine Citrate, Psorisis (EU)										94,722	121,615	149,899	179,629	210,861	243,657
Total Product Sales										**94,722**	**121,615**	**149,899**	**179,629**	**210,861**	**243,657**
Expenses						9,000									
Cost of Goods Sold						5,000				14,208	18,242	17,988	19,759	21,086	24,366
%COGS						%				15%	15%	12%	11%	10%	10%
Research and Development	2,485	133	500	1,200	1,300	3,133	7,000	10,000	10,200	12,000	12,240	12,485	12,734	12,989	13,249
%R&D															
General expenses	8,830	1,228	1,250	1,275	1,300	5,053	5,154	5,164	5,268	5,373	5,480	5,590	5,702	5,816	5,932
%SG&A															
Total expenses	**11,315**	**1,361**	**1,750**	**2,475**	**2,600**	**13,186**	**12,154**	**15,164**	**15,468**	**31,581**	**35,963**	**36,063**	**38,196**	**39,891**	**43,547**
Operating Income (Loss)	(11,315)	(1,361)	(1,750)	(2,475)	(2,600)	(13,186)	(12,154)	(15,164)	(15,468)	63,140	85,653	113,836	141,433	170,970	200,110
Derivative gain	1,360														
Interest expense	(410)	(1,341)													
Interest income	1														
Other income(expense)	3,601	11													
Total other income (expense)	**4,552**														
Pretax Income	**(6,763)**	**(2,691)**	**(1,750)**	**(2,475)**	**(2,600)**	**(13,186)**	**(12,154)**	**(15,164)**	**(15,468)**	**63,140**	**85,653**	**113,836**	**141,433**	**170,970**	**200,110**
Income Tax Benefit (Provision)												5,692	14,143	25,646	40,022
Tax Rate												5%	10%	15%	20%
Net loss from continuing operations	(6,763)	(2,691)	(1,750)	(2,475)	(2,600)	(13,186)	(12,154)	(15,164)	(15,468)	63,140	85,653	119,528	127,290	145,325	160,088
Discontinued Operations															
(Loss)/gain on disposal															
Loss on discontinued operations	(82)	(1)				(1)									
Total discontinued operations	(82)														
Comprensive Loss	**(6,845)**	**(2,692)**	**(1,750)**	**(2,475)**	**(2,600)**	**(13,186)**	**(12,154)**	**(15,164)**	**(15,468)**	**63,140**	**85,653**	**119,528**	**127,290**	**145,325**	**160,088**
GAAP-EPS	**(0.70)**	**(0.22)**	**(0.08)**	**(0.08)**	**(0.08)**	**(0.54)**	**(0.37)**	**(0.41)**	**(0.41)**	**1.67**	**2.24**	**3.08**	**3.24**	**3.65**	**3.97**
GAAP EPS (dil)	(0.70)														
Wgtd Avg Shrs (Bas) - '000s	9,720	11,987	21,999	32,021	32,053	24,515	32,422	36,851	37,331	37,817	38,310	38,810	39,315	39,828	40,347
Wgtd Avg Shrs (Dil) - '000s	9,720	11,987	21,999	32,021	32,053	24,515	32,422	36,851	37,331	37,817	38,310	38,810	39,315	39,828	40,347

Source: Company reports and Maxim

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DISCLOSURES



Maxim Group LLC Ratings Distribution			As of: 05/16/16
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	**86%**	**35%**
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither significantly outperform nor underperform its relevant index over the next 12 months.	**13%**	**26%**
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	**1%**	**0%**
	**See valuation section for company specific relevant indices*		

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I, Jason McCarthy, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

Maxim Group makes a market in Rock Creek Pharmaceuticals

Maxim Group managed/co-managed/acted as placement agent for an offering of the securities for Rock Creek Pharmaceuticals in the past 12 months.

Maxim Group received compensation for investment banking services from Rock Creek Pharmaceuticals in the past 12 months.

Maxim Group expects to receive or intends to seek compensation for investment banking services from Rock Creek Pharmaceuticals in the next 3 months.

An affiliate of Maxim Group beneficially owns warrants/shares in Rock Creek Pharmaceuticals .

RCPI: For RockCreek we use the BTK as the relevant index

Valuation Methods

RCPI: Our therapeutic model assumes that anatabine citrate is approved and launched in 2020. We expect the initial indication to be for mild to moderate psoriasis. Our model assumes a risk adjustment due to the early stage of clinical development. We then apply a 30% discount to our free-cash-flow, discounted-EPS, and sum-of-the-parts models, which are equally weighted to arrive at our price target.

Price Target and Investment Risks

RCPI: RockCreek faces multiple risks associated with the company. These include but are not limited to: The pace and success of drug development activities; The possible out-licensing of any product candidates developed; obtaining regulatory approvals for any product candidates developed; the pace of development of new intellectual property for any product candidates developed; The company's ability to market and sell their products; and the ability to secure financing necessary to operate and grow the business. There can be no assurance that an IND filed with the FDA in the U.S. will result in the actual initiation of clinical trials in the U.S. or that the company's products will ultimately be approved or achieve or maintain expected levels of market acceptance in the U.S. or anywhere else.

RISK RATINGS

Risk ratings take into account both fundamental criteria and price volatility.

Speculative – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. Price Volatility: Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

High – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. Price Volatility: The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

Medium – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

Low – Fundamental Criteria: This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST

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