

Healthcare: Biotechnology
Company Update
KemPharm, Inc. | KMPH - \$9.43 - NASDAQ | Buy

Estimates Changed

Stock Data

52-Week Low - High	\$1.94 - \$22.08
Shares Out. (mil)	18.85
Mkt. Cap.(mil)	\$177.76
3-Mo. Avg. Vol.	1,789,052
12-Mo.Price Target	\$28.00
Cash (mil)	\$85.1
Tot. Debt (mil)	\$0.0
Cash (mil): Proforma cash includes 3Q20 \$5.3M balance, recent net raises of \$87.8M, and retirement of all debt.	
Tot. Debt (mil): proforma debt due to recent retirement of all \$65.9M in debt	

Revenue (\$ millions)

Yr Dec	—2019—	—2020E—	—2021E—
		Curr	Curr
1Q	-	2.1A	50.0E
2Q	-	6.9A	2.0E
3Q	-	1.9A	2.0E
4Q	-	2.0E	2.0E
YEAR	12.8A	12.9E	56.0E

EPS \$

Yr Dec	—2019—	—2020E—	—2021E—
		Curr	Curr
1Q	-	(1.92)A	2.54E
2Q	-	0.22A	(0.08)E
3Q	-	(0.68)A	(0.08)E
4Q	-	(0.64)E	(0.09)E
YEAR	(13.23)A	(2.72)E	2.05E
P/E	NM	NM	4.6x

KMPH One-Year Price and Volume History


KMPH: FDA Approves Azstarys, Mgmt Sounds Confident About \$48M Milestone

Azstarys received FDA approval as a once-daily drug for ADHD in patients six years or older. Partner Corium will begin selling Azstarys in 2H21. An approval milestone has been earned and is only one of two potential amounts to be received due to approval. There is an undisclosed amount that was triggered simply by approval, and another amount that could potentially bring the sum of both payments up to \$48M. We look forward to milestone magnitude clarity within 30 days.

- Azstarys (KP415) received FDA approval late last night as a once-daily drug for treating ADHD in patients at least six years old. The drug is a combination of KMPH's proprietary and long acting prodrug serdexmethylphenidate to extend durability of effect, and immediate release dexmethylphenidate to minimize the onset of action-MPH. Commercialization partner Corium will begin selling Azstarys in 2H21.
- We note that an approval milestone to be paid to KMPH from Corium has been earned and that it is only one of two potential amounts to be received as a result of the approval. There is a currently undisclosed amount that was triggered simply by approval, and another amount that could potentially bring the sum of both payments up to \$48M. KMPH sounded quite confident on today's conference call that the total payment from Gurnet Point Capital should be \$48M, but it also could be lower given that KMPH and Gurnet have yet to finalize negotiating the exact milestone payment amount, as that amount is entirely driven by the differentiation of the Azstarys label, specifically an onset of action of 30 minutes and a durability of effect of 13 hours. The portion of the label to be interpreted by Gurnet and KMPH, thereby driving the total milestone amount, is the Phase 3 efficacy graph of Azstarys versus placebo (i.e., difference in LS mean SKAMP scores). We expect a press release today sometime from Corium about the drug's approval and its potentially differentiating attributes, but it is Gurnet that actually pays the milestones and thus the Corium press release will not address the magnitude of any potential milestone payments. Gurnet must pay KMPH all approval-related milestones within 30 days, so we will know the answer soon enough.
- We expect that Corium intends to focus on the absence of any statistically significant reduction in height or weight in patients taking Azstarys for 12 months versus the general population, as well as the onset, consistency, and durability of effect as conveyed in the Phase 3 efficacy graph in the label, but it does not appear to us that abuse potential is a differentiating attribute. There has certainly been little innovation in the ADHD drug market in recent years, so it is entirely possible that any amount of favorable differentiation, in the absence of any unfavorable differentiating qualities, is enough to drive adoption, thereby generating potentially substantial royalties for KMPH (up to the *(text continued on page 2)*)

(KMPH traded recently at \$13.61 at 11:20AM EST)

Important Disclosures & Regulation AC Certification(s) are located on page 5 to 6 of this report.

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- mid-twenties percentage of U.S. net sales and up to the mid-single digits percentage of ex-U.S. net sales)
KMPH may also be eligible for up to \$468M in regulatory and sales milestones.

VALUATION

Our 12-month price target of \$28/share is based on a DCF analysis using a 35% discount rate that is applied to all cash flows and the terminal value, which is based on a 3x multiple of our projected 2031 operating income of about \$326 million. Our valuation is driven by U.S., Canadian, and E.U. commercial success with KP415 in ADHD, and U.S. commercial success with APADAZ in acute pain. Commercial success outside these territories with any of these assets, or any commercial success with its other assets, would provide upside to our valuation.

Factors which could impede the achievement of our target price include, but are not limited to: (1) failure and/or setbacks of pipeline candidates in clinical studies; (2) failure of pipeline candidates to gain regulatory approval; departure of key personnel; and (4) smaller than projected commercial opportunity due to changes in market size, competitive landscape, and drug pricing and reimbursement.

RISKS

Clinical risk. KMPH's clinical staged products could fail to deliver statistically significant results in clinical trials, substantially reducing the value of KMPH's product candidates and therefore our price target.

Regulatory risk. Even if successful in the clinic, KMPH's products could fail to be approved by domestic and/or foreign regulatory bodies, which would reduce KMPH's value and therefore our price target.

Financing risk. KMPH will need additional capital to fund its operations, and such financing may not occur or it could be substantially dilutive to existing investors.

Competitive risk. For any current or future approved KMPH products, they may not be well adopted in a competitive marketplace, which would adversely affect KMPH's value and therefore our price target.

High stock price volatility. This issue is common among small-cap biotechnology companies with relatively low trading volumes.

COMPANY DESCRIPTION

KemPharm is a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through its proprietary LAT (Ligand Activated Therapy) technology. KemPharm utilizes its proprietary LAT technology to generate improved prodrug versions of FDA-approved drugs as well as to generate prodrug versions of existing compounds that may have applications for new disease indications. KemPharm's prodrug product candidate pipeline is focused on the high need areas of attention deficit hyperactivity disorder, or ADHD, and stimulant use disorder. KemPharm's co-lead clinical development candidates for the treatment of ADHD, KP415 and KP484, are both based on a prodrug of d-methylphenidate, but have differing duration/effect profiles. In addition, KemPharm has received FDA approval for APADAZ, an immediate-release combination product containing benzhydrocodone, a prodrug of hydrocodone, and acetaminophen.

KemPharm, Inc. Income Statement		Jonathan Aschoff, Ph.D. (646) 616-2795 jaschoff@roth.com												
Fiscal Year ends December														
(in 000, except per share items)														
	2018A	2019A	1Q20A	2Q20A	3Q20A	4Q20E	2020E	1Q21E	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E
APADAZ profit sharing revenue								50000	2000	2000	2000	-	1,268	2,169
KP415 related revenue												56,000	17,697	54,377
Total revenue	-	12,839	2,089	6,908	1,925	2,000	12,922	50,000	2,000	2,000	2,000	56,000	18,965	56,547
COGS														
Gross profit	0	12839	2089	6908	1925	2000	12922	50000	2000	2000	2000	56,000	18,965	56,547
Royalty and direct contract acq. costs	0	2945	663	642			1,305					-		
R&D	41,759	19,415	2,126	1,954	1,709	1,726	7,515	1,812	1,903	1,998	2,098	7,812	8,202	8,612
SG&A	14,144	10,816	3,075	1,719	1,429	1,443	7,666	1,458	1,472	1,487	1,502	5,919	6,097	6,279
Total operating expenses	55,903	33,176	5,864	4,315	3,138	3,169	16,486	3,270	3,375	3,485	3,600	13,731	14,299	14,892
Operating income	(55,903)	(20,337)	(3,775)	2,593	(1,213)	(1,169)	(3,564)	46,730	(1,375)	(1,485)	(1,600)	42,269	4,666	41,655
Interest exp from amort debt issuance costs/discount	(1,618)	(1,656)	(571)	(574)	(578)	(580)	(2,303)	(5,000)				(5,000)		
Interest expense on principal	(5,469)	(4,858)	(1,260)	(1,197)	(1,163)	(1,140)	(4,760)	(65)				(65)		
Fair val adjust from derivative and warrant liability	5,976	1,998	75	(3)	(137)	(140)	(205)	(140)	(140)	(140)	(140)	(560)		
Interest and other income (expense), net	422	309	(223)	40	48	40	(95)	100	90	85	75	350	368	386
Net income (pretax)	(56,592)	(24,544)	(5,754)	859	(3,043)	(2,989)	(10,927)	41,625	(1,425)	(1,540)	(1,665)	36,995	5,034	42,041
Income tax expense (benefit)	(126)	(22)			(34)	(30)	(64)	(30)	(30)	(30)	(30)	(120)		
Net income	(56,466)	(24,522)	(5,754)	859	(3,009)	(2,959)	(10,863)	41,655	(1,395)	(1,510)	(1,635)	37,115	5,034	42,041
EPS basic	(50.39)	(13.23)	(1.92)	0.22	(0.68)	(0.64)	(2.72)	2.54	(0.08)	(0.08)	(0.09)	2.05	0.25	2.02
EPS diluted	(50.39)	(13.23)	(1.92)	0.22	(0.68)	(0.64)	(2.72)	2.54	(0.08)	(0.08)	(0.09)	2.05	0.25	2.02
Basic shares outstanding	1,121	1,853	3,005	3,948	4,426	4,603	3,995	16,390	18,501	18,686	18,873	18,112	19,816	20,807
Diluted shares outstanding	1,121	1,853	3,005	3,948	4,426	4,603	3,995	16,390	18,501	18,686	18,873	18,112	19,816	20,807

Source: SEC filings, company press releases, and ROTH Capital Partners

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Within the last twelve months, ROTH has received compensation for investment banking services from KemPharm, Inc..

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Shares of KemPharm, Inc. may not be eligible for sale in one or more states.

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Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 03/03/21	
			Count	Percent
Buy [B]	312	79.39	193	61.86
Neutral [N]	51	12.98	22	43.14
Sell [S]	2	0.51	1	50.00
Under Review [UR]	28	7.12	20	71.43

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

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Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

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