

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): March 30, 2022

KemPharm, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-36913
(Commission File Number)

20-5894398
(IRS Employer Identification No.)

1180 Celebration Boulevard, Suite 103, Celebration, FL
(Address of Principal Executive Offices)

34747
(Zip Code)

Registrant's Telephone Number, Including Area Code: (321) 939-3416

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---------------------|-------------------|--|
| Common Stock | KMPH | The Nasdaq Stock Market LLC (Nasdaq Global Select Market) |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 30, 2022, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2021, as well as information regarding a conference call and live audio webcast with slide presentation to discuss its financial results and corporate updates scheduled for Wednesday, March 30, 2022 at 5:00 p.m. ET. A copy of the press release and presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K. The information contained in the press release and presentation, furnished as Exhibit 99.1 and Exhibit 99.2, respectively, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and is not incorporated by reference into any of KemPharm's filings under the Securities Act of 1933, as amended, or the Securities Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description |
|--------------------|---|
| 99.1 | Press Release dated March 30, 2022. |
| 99.2 | Presentation dated March 30, 2022. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KemPharm, Inc.

Date: March 30, 2022

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, CPA
Chief Financial Officer, Secretary and Treasurer



KemPharm Reports Fourth Quarter and Fiscal Year 2021 Financial Results and Corporate Updates

Conference Call and Live Audio Webcast with Slide Presentation Scheduled for Today, March 30, 2022, 5:00 p.m. ET

Corporate and Regulatory Highlights

- Announced strategic focus on developing and commercializing therapeutics targeting rare central nervous system (CNS) and neurodegenerative conditions;
- Advancing development of KP1077, a serdexmethylphenidate (SDX) based product candidate for idiopathic hypersomnia (IH), as KemPharm's lead candidate:
 - Pre-Investigational New Drug (IND) process with the U.S. Food and Drug Administration (FDA) successfully completed in February 2022;
 - IND filing expected as early as the second quarter of 2022; Phase 2 trial initiation expected in the second half of 2022; and
 - Reported data from the Phase 1 clinical trial exploring the safety and pharmacokinetics (PK) of "higher-dose" SDX which validates selection of KP1077 as lead product candidate.
- AZSTARYS® national launch accelerating; full national sales team in place as of January 31, 2022, growing payor access;
- KemPharm named 2021 David J. Gury Company of the Year by BioFlorida; and
- Earned \$1.975 million fee in first quarter of 2022 following FDA approval of Corium, Inc.'s product, ADLARITY®.

Financial Highlights

- Reported quarter ended December 31, 2021 (Q4 2021) revenue of \$2.6 million and FY 2021 revenue of \$28.7 million; and
- Total cash, cash equivalents and long-term investments was \$127.8 million as of December 31, 2021.

Celebration, FL – March 30, 2022 – KemPharm, Inc. (NasdaqGS: KMPH) (KemPharm, or the Company), a specialty pharmaceutical company focused on the discovery and development of novel treatments for rare central nervous system (CNS) diseases, today reported its financial results for the fourth quarter and year ended December 31, 2021.

"KemPharm advanced on multiple fronts during the fourth quarter of 2021 and into early 2022, cementing the past twelve months as the most substantial in KemPharm's history," stated Travis Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "In January, we announced our strategic focus on developing and commercializing therapeutics targeting rare CNS and neurodegenerative conditions starting with KP1077. The data released earlier this month from the Phase 1 clinical trial exploring the safety and PK of 'higher dose SDX,' affirms the opportunity to develop multiple SDX-based drug candidates, led by KP1077 for the treatment of IH, a rare sleep disorder with limited treatment options. Our recent interactions with the FDA have confirmed that we may proceed with the submission of an IND application for KP1077, which we expect to file as early as the second quarter of 2022. Upon clearance of the IND, we plan to initiate a Phase 2 clinical trial of KP1077 in IH later this year with a second trial in narcolepsy targeted to begin as early as the second half of 2022. In addition, we remain active on the business development front with the goal of acquiring or licensing complimentary clinical stage assets in rare CNS and neurodegenerative diseases."

“As KemPharm focuses on advancing KP1077 and expanding our development pipeline, we remain bullish on the potential for the commercial success of AZSTARYS®, which is now being commercialized nationally by Corium. There have been significant gains in payor access, and prescription volume is beginning to grow. If this growth continues along the same trajectory observed since the beginning of 2022, the potential to achieve the initial sales milestones provided in the licensing agreement with an affiliate of Gurnet Point Capital becomes more tangible.”

“Supporting these strategic and product development efforts is our strong financial position. With \$127.8 million in cash, cash equivalents and long-term investments as of December 31, 2021, our current capital resources enable us to advance our internal pipeline while also potentially seeking external opportunities. The strength of our capital position sets us apart from many other development-stage biopharmaceutical companies, particularly in this challenging capital market environment. Our existing \$50 million share repurchase program, which extends through 2023, also provides a mechanism to return value to shareholders as we achieve success.”

Q4 and Full-Year 2021 Financial Results:

KemPharm’s revenue for Q4 2021 was \$2.6 million, as compared to Q4 2020 revenue of \$2.4 million. Q4 2021 revenue was derived primarily from \$2.0 million in service fee revenue, and approximately \$0.6 million of various royalty payments under the license agreement which covers AZSTARYS. The contracts under which service fee revenue is derived will end on March 31, 2022, although some amount of service fee revenue is expected to continue beyond that date.

KemPharm’s net loss for Q4 2021 was (\$2.7) million, or (\$0.08) per basic and diluted share, compared to a net loss of (\$4.9) million, or a loss of (\$1.07) per basic and diluted share for the same period in 2020. Net loss for Q4 2021 was driven primarily by a loss from operations of (\$2.8) million, partially offset by net interest and other income of \$0.1 million. The net operating loss of (\$2.8) million for Q4 2021 was a decrease of (\$0.4) million compared to net operating loss of (\$3.2) million in the same period in 2020.

For FY 2021, KemPharm reported revenue of \$28.7 million, which was primarily driven by \$20.6 million in milestone and royalty revenue received under the license agreement which covers AZSTARYS, and approximately \$8.1 million derived under service fee arrangements and related reimbursements. FY 2020 revenue was \$13.3 million.

KemPharm’s net loss attributable to common stockholders for FY 2021 was (\$62.9) million, or (\$2.11) per basic and diluted share, compared to net loss attributable to common stockholders of (\$12.8) million, or (\$3.21) per basic and diluted share for FY 2020. Net loss attributable to common stockholders for FY 2021 was driven primarily by aggregate non-cash deemed dividends of (\$54.3) million, or (\$1.83) per basic and diluted share, which were recognized as a result of the warrant inducement transactions completed in the first half of 2021, a non-cash net loss on extinguishment of debt of (\$16.1) million, or (\$0.54) per basic and diluted share related to the debt extinguishment in Q1 2021, partially offset by net income from operations of \$7.7 million.

As of December 31, 2021, total cash, cash equivalents and long-term investments was \$127.8 million, which was a decrease of \$3.7 million compared to \$131.5 million as of September 30, 2021, driven in part by share repurchases of \$2.4 million which were settled during Q4 2021. Based on the Company's current operating forecast, existing cash, cash equivalents and long-term investments are expected to be sufficient to continue operations through and beyond 2025.

Conference Call Information:

KemPharm will host a conference call and live audio webcast with slide presentation on today at 5:00 p.m. ET, to discuss its corporate and financial results for the fourth quarter of 2021 and fiscal year of 2021.

| | |
|--------------------------|--|
| Telephone Access: | To access the conference call telephonically, interested participants and investors will be required to register via the following online form: http://www.directeventreg.com/registration/event/8038872 . Once registered, all individuals will be provided with participant dial-in numbers, a passcode, and a registrant ID, which can then be used to access the conference call. Participants may register at any time. It is recommended that the registration process be completed at least 15 minutes prior to the start of the call. |
| Webcast Access: | The live audio webcast with slide presentation will be accessible via the Investor Relations section of KemPharm's website, http://investors.kempharm.com/ . An archive of the webcast and presentation will be available for 90 days beginning at approximately 6:00 p.m. ET, on Wednesday, March 30, 2022. |

About KemPharm:

KemPharm is a specialty pharmaceutical company focused on the discovery and development of novel treatments for rare central nervous system (CNS) diseases through its proprietary LAT® (Ligand Activated Therapy) platform technology. KemPharm utilizes its proprietary LAT® platform 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 idiopathic hypersomnia (IH) and other CNS/rare diseases. In addition, the U.S. Food and Drug Administration (FDA) has approved AZSTARYS®, a new once-daily treatment for ADHD in patents age six years and older containing KemPharm's prodrug, serdexmethylphenidate (SDX), which is being commercialized by Corium, Inc. in the U.S., and APADAZ®, an immediate-release combination product containing benzhydrocodone, KemPharm's prodrug of hydrocodone, and acetaminophen, which is being commercialized by KVK-Tech, Inc. in the U.S. For more information on KemPharm and its pipeline of prodrug product candidates visit www.kempharm.com or connect with us on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

Caution Concerning Forward Looking Statements:

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation and which can be identified by the use of words such as “may,” “will,” “expect,” “project,” “estimate,” “anticipate,” “plan,” “believe,” “potential,” “should,” “continue,” “could,” “intend,” “target,” “predict,” or the negative versions of those words or other comparable words or expressions, although not all forward-looking statements contain these identifying words or expressions. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements include statements regarding the promise and potential impact of our preclinical or clinical trial data, including without limitation the timing and results of any clinical trials or readouts, the timing or results of any IND applications, the potential benefits of KP1077, SDX or any other product candidates for any specific disease indication, the potential benefits of any of KemPharm’s product candidates, the success or timing of the launch or commercialization of AZSTARYS or any other products or related sales milestones, the sufficiency of cash to fund operations, our plans or ability to seek funding, our plans with respect to our share repurchase program, and our strategic and product development objectives. These forward-looking statements are based on information currently available to KemPharm and its current plans or expectations and are subject to a number of known and unknown uncertainties, risks and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These and other important factors are described in detail in the “Risk Factors” section of KemPharm’s Annual Report on Form 10-K for the year ended December 31, 2021, and KemPharm’s other filings with the Securities and Exchange Commission.

While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

This press release also may contain estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

KemPharm Contacts:

Tiberend Strategic Advisors, Inc.
Jason Rando/Daniel Kontoh-Boateng
jrando@tiberend.com
dboateng@tiberend.com

KEMPHARM, INC.
STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

| | Year Ended December 31, | |
|--|--------------------------------|--------------------|
| | 2021 | 2020 |
| Revenue | \$ 28,650 | \$ 13,288 |
| Operating expenses: | | |
| Royalty and direct contract acquisition costs | 2,059 | 1,305 |
| Research and development | 10,161 | 8,843 |
| General and administrative | 8,701 | 7,921 |
| Severance expense | - | 828 |
| Total operating expenses | <u>20,921</u> | <u>18,897</u> |
| Income (loss) from operations | <u>7,729</u> | <u>(5,609)</u> |
| Other (expense) income: | | |
| Loss on extinguishment of debt | (16,096) | - |
| Interest expense related to amortization of debt issuance costs and discount | (150) | (2,305) |
| Interest expense on principal | (226) | (4,785) |
| Fair value adjustment related to derivative and warrant liability | (26) | (184) |
| Interest and other income, net | 248 | 89 |
| Total other expense | <u>(16,250)</u> | <u>(7,185)</u> |
| Loss before income taxes | <u>(8,521)</u> | <u>(12,794)</u> |
| Income tax (expense) benefit | <u>(34)</u> | <u>34</u> |
| Net loss | <u>(8,555)</u> | <u>(12,760)</u> |
| Deemed dividend | <u>(54,342)</u> | <u>-</u> |
| Net loss attributable to common stockholders | <u>\$ (62,897)</u> | <u>\$ (12,760)</u> |
| Basic net loss per share of common stock: | | |
| Net loss attributable to common stockholders | <u>\$ (2.11)</u> | <u>\$ (3.21)</u> |
| Diluted net loss per share of common stock: | | |
| Net loss attributable to common stockholders | <u>\$ (2.11)</u> | <u>\$ (3.21)</u> |
| Weighted average number of shares of common stock outstanding: | | |
| Basic | <u>29,766,347</u> | <u>3,980,975</u> |
| Diluted | <u>29,766,347</u> | <u>3,980,975</u> |

KEMPHARM, INC.
BALANCE SHEETS
(in thousands, except share and par value amounts)

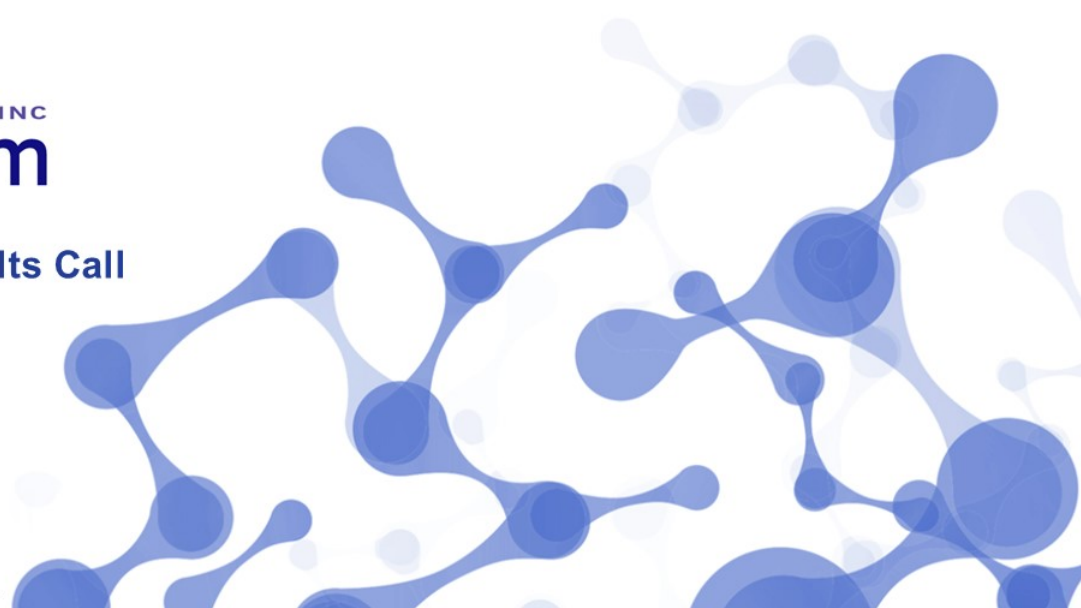
| | December 31, | |
|---|--------------|-----------|
| | 2021 | 2020 |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 112,346 | \$ 4,213 |
| Accounts and other receivables | 1,528 | 2,579 |
| Prepaid expenses and other current assets | 1,182 | 1,481 |
| Restricted cash | - | 109 |
| Total current assets | 115,056 | 8,382 |
| Property and equipment, net | 884 | 1,039 |
| Operating lease right-of-use assets | 1,141 | 1,350 |
| Long-term investments | 15,422 | - |
| Other long-term assets | 438 | 438 |
| Total assets | \$ 132,941 | \$ 11,209 |
| Liabilities and stockholders' equity (deficit) | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 3,038 | \$ 6,647 |
| Current portion of operating lease liabilities | 356 | 327 |
| Current portion of loans payable | - | 390 |
| Other current liabilities | 836 | 172 |
| Total current liabilities | 4,230 | 7,536 |
| Convertible notes, less current portion, net | - | 67,658 |
| Derivative and warrant liability | 330 | 304 |
| Operating lease liabilities, less current portion | 1,232 | 1,587 |
| Loans payable, less current portion | - | 391 |
| Other long-term liabilities | 31 | 145 |
| Total liabilities | 5,823 | 77,621 |
| Stockholders' equity (deficit): | | |
| Preferred stock: | | |
| Series A convertible preferred stock, \$0.0001 par value, no shares authorized, issued or outstanding as of December 31, 2021; 9,578 shares authorized, 9,577 shares issued and no shares outstanding as of December 31, 2020 | - | - |
| Series B-1 convertible preferred stock, \$0.0001 par value, no shares authorized, issued or outstanding as of December 31, 2021; 1,576 shares authorized and issued and no shares outstanding as of December 31, 2020 | - | - |
| Series B-2 convertible preferred stock, \$0.0001 par value, no shares authorized, issued or outstanding as of December 31, 2021; 27,000 shares authorized and issued and no shares outstanding as of December 31, 2020 | - | - |
| Undesignated preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2021; 9,961,846 shares authorized, no shares issued or outstanding as of December 31, 2020 | - | - |
| Common stock, \$0.0001 par value, 250,000,000 shares authorized, 35,325,801 shares issued and 35,005,640 shares outstanding as of December 31, 2021; 4,537,321 shares issued and outstanding as of December 31, 2020 | 4 | 0 |
| Additional paid-in capital | 396,957 | 192,062 |
| Treasury stock, at cost | (2,814) | - |
| Accumulated deficit | (267,029) | (258,474) |
| Total stockholders' equity (deficit) | 127,118 | (66,412) |
| Total liabilities and stockholders' equity (deficit) | \$ 132,941 | \$ 11,209 |



KemPharm ^{INC}

Q4 and FY 2021 Results Call

March 30, 2022



Trademarks herein are held by their respective owners.

Cautionary Note Regarding Presentation Information

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While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to this presentation.

This presentation also may contain estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.



KEMPHARM VALUE PROPOSITION

Innovative pharmaceutical company discovering and developing novel treatments for CNS and rare diseases

Two FDA approved and partnered medications, AZSTARYS® and APADAZ®, validate approach and science

Focus on high-value areas with significant unmet needs in CNS/rare disease with potential to internally commercialize

FY 2021 Year in Review: KemPharm's Transformation

Corporate and Regulatory Highlights

- Jan 8: Regained listing on The Nasdaq Capital Market
- Mar 2: FDA approval of AZSTARYS®
- May 7: DEA designates SDX as a CIV controlled substance
- Jun 9: Added to Russell 2000 and 3000 indexes
- Jul 21: Commercial launch of AZSTARYS
- Oct 19: Up-listed to The Nasdaq Global Select Market
- Dec 13: Added to Nasdaq Biotech Index
- Dec 13: Named 2021 David J Gury Company of the Year by BioFlorida
- Dec 20: \$50M Share Repurchase Program announced

Financial Highlights

- Jan 8: Complete \$50M secondary offering
- Jan 12: Repaid \$30.3M in debt, converted \$31.5M into preferred shares, leaving a remainder of \$7.6M due Mar 31, 2023
- Jan 26: Complete warrant exercise inducement transaction with gross proceeds of approx. \$44M
- Feb 8: Repaid remainder of debt
- Jun 18: Complete second warrant exercise inducement transaction, eliminating substantial portion of outstanding warrant overhang and gross proceeds of approx. \$39.1M
- Dec 31: End year with \$127.8M in cash, cash equivalents and long-term investments, and \$0 debt



KemPharm: Q4 2021 and Recent Highlights

- ✓ KP1077: Substantial high-value opportunity with significant unmet need
- ✓ “Higher Dose” SDX data suggest targeted pharmacodynamic effects that could benefit patients with IH and other sleep disorders

Initiation of
KP1077
Development
Program

Opportunities
to Further
Expand
Pipeline

- ✓ Continuing efforts to build a highly differentiated pipeline of development assets
- ✓ Focused on high-value areas with significant unmet needs in **CNS/rare disease** with potential to internally commercialize

- ✓ Full national team in place
- ✓ Sales force size doubled in early 2022
- ✓ **Currently 110M+ covered commercial lives**

AZSTARYS®
Launch
Gaining
Traction

Strong
Balance Sheet
to Support
Value Creation

- ✓ Cash, cash equivalents and long-term investments of **\$127.8M** as of Dec 31, 2021
- ✓ Solid balance sheet supports development efforts and other pipeline expansion activities
- ✓ **Available capital extends cash runway beyond 2025**



Pipeline of Product Candidates with Substantial Milestones in 2022 and Beyond

| Indication | Product Candidate | Phase of Development | Anticipated Timing of Next Milestone |
|---|-------------------|---|--------------------------------------|
| Rare Sleep Disorders | | | |
| Idiopathic Hypersomnia (IH) | KP1077 | Phase 2 | Q3 2022 |
| Narcolepsy Type I and II | KP1077 | Phase 2 | Q4 2022 |
| Sleep Disorders | TBD | In-licensing, acquisition or internal candidate | H2 2022 |
| First-in-Class Therapy | | | |
| Stimulant Use Disorder (SUD) | KP879 | Phase 2 | External Funding and Collaborations |
| In-licensed or Acquired Product(s) | | | |
| CNS or Related | TBD | Phase 2 or later | H2 2022 |



SDX Product Candidate: KP1077

For the Treatment of Idiopathic Hypersomnia (IH)



Idiopathic Hypersomnia (IH)

- There are 10.3 IH patients per 100,000 people in the US¹
 - ~37,000 diagnosed IH patients actively seeking treatment²
 - Patient population may be much larger (not seeking treatment, undiagnosed, misdiagnosed)
- Symptoms are highly debilitating – **IH can be more debilitating than narcolepsy**
 - Chronic daytime sleepiness
 - Long and unrefreshing naps
 - Extreme difficulty waking (sleep inertia and/or sleep drunkenness)
 - Severe brain fog
 - Some experience excessively long sleep times (~25% of patients “long sleepers”, >10hrs)
- IH patients report memory problems, errors in habitual activities, mind blank and attention problems as part of their disability
 - KOLs identified depression as a common comorbidity encountered with patients
 - Patient survey data indicates that current medication effectiveness was poorly rated at 5.4/10⁽³⁾

Sources: (1) <https://doi.org/10.1093/sleep/zsv061.624>

(2) <https://www.sleepcountshcp.com/what-is-idiopathic-hypersomnia>

(3) <https://www.sleepcountshcp.com/idiopathic-hypersomnia-treatment-options>



KP1077 Product Candidate Overview

- 100% Serdexmethylphenidate (SDX) product with multiple dosing options depending on patient needs
 - Dosed either QD (1x daily at bedtime) or BID (2x daily at bedtime and upon waking)
- Features and benefits already demonstrated:
 - **SDX has already been designated C-IV by DEA**
 - No DDI potential with hormonal contraceptives and antidepressants
- Potential additional features and benefits to be studied:
 - **Greater tolerability** could allow for higher, more effective dosing (i.e. greater efficacy)
 - Dosing regimen addresses the two primary issues associated with IH
 - Night-time dosing addresses sleep inertia (waking)
 - Morning dosing addresses daytime brain fog; considered most problematic symptom of IH
 - **Lessened effect on heart rate and blood pressure** vs. other MPH products
- Orphan drug designation potential
 - Fast-track eligible
 - Break-through designation eligible
- No generic equivalent and not substitutable; **solid IP through 2037** and potentially beyond



MOA¹ and Trial Data Suggest KP1077 is Well Positioned to Demonstrate Efficacy

- **Ritalin and Ritalin SR (racemic methylphenidate) are indicated to treat narcolepsy²**
 - *Methylphenidate-based products have demonstrated some efficacy in treating excessive daytime sleepiness associated with narcolepsy, a similar rare sleep disorder with the primary symptom of Excessive Daytime Sleepiness (EDS)*
- **Phase 1 trial results suggest SDX at higher-doses can produce the desired effects of wakefulness and a feeling of being energized in subjects with a history of high-dose stimulant use**
 - *Additional effects of hypervigilance and insomnia were also indicative of the potential to address excessive sleepiness*
 - *Trial data collected during AZSTARYS development provides further evidence of potential effects and pharmacokinetics*

Drowsiness/Alertness VAS^a

(bipolar scale: 0 to 100)

Baseline Score Range: 37 – 50

Peak Score Range: 67 - 89

Energized VAS^b

(unipolar scale: 0 to 100)

Baseline Score Range: 15 - 20

Peak Score Range: 61 - 82

Notes:

(a) Drowsiness/Alertness Visual Analogue Scale is an at-the-moment bipolar scale where a score of 50 is neither drowsy or alert, a score of 0 is Strong Drowsiness and a score of 100 is strong Alertness

(b) Energized Visual Analogue Scale (VAS) is an at-the-moment unipolar scale measuring the feeling of excess energy where a score of 0 is "definitely no" energy and 100 is "definitely so"

(1) Mechanism of action

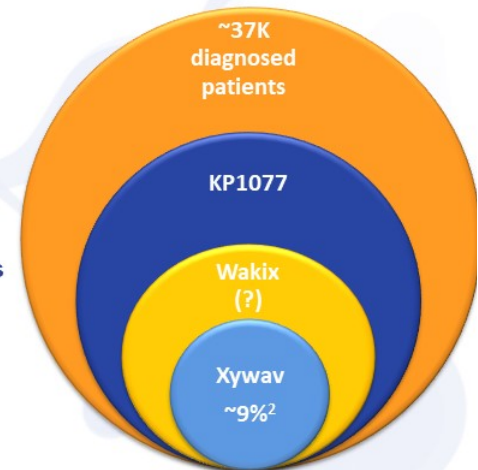
(2) Ritalin Package Insert



KP1077 Could Capture a Large Share of the IH Market Based on Potential Clinical Differentiation and Combination Use

- It is estimated that ~37K patients are currently diagnosed with IH and actively seeking treatment¹
- Xywav® received FDA approval in August 2021 as the first therapy for IH
- According to analysts, Xywav projected sales are ~\$300 million for IH by the end of 2025
 - Assuming an average price of ~\$94K per patient per year, IH patient share for Xywav by 2025 is expected to be ~3,200 patients (~9% of diagnosed patients)²
- Potential factors that may result in higher adoption of KP1077, compared to Xywav (approved) or Wakix® (in development):
 - Different MOA than Xywav suggests possible concomitant use; **75% of patients in Xywav IH trial also took stimulant medication**
 - **Improved efficacy of KP1077** due to increased tolerability vs. other stimulants
 - **KP1077 safety profile** related to C-IV, improved cardiovascular safety and lack of significant DDI potential
 - Xywav barriers to uptake including AEs, REMS and GHB stigma
 - Xywav promotion and disease awareness helps all marketed products
 - Wakix barriers to uptake related to DDI potential and different MOA

Illustrative Market Share based on Potential Differentiation



Sources: (1) <https://www.sleepcountshcp.com/what-is-idiopathic-hypersomnia>
(2) <https://investor.iazzpharma.com/investors/events-presentations>



Business Development Focus

- **Maximizing Value Potential of SDX**
- **Pipeline Additions Through In-Licensing**



Platform Potential of SDX

- The properties of SDX opens the door to explore indications outside ADHD and IH:
 - The **only C-IV methylphenidate-based product**; all others are C-II
 - Unique PK profile allowing for gradual and continuous release throughout the day
 - Currently, no generic equivalent for SDX and not substitutable
- SDX expected to provide benefit to patients with both Type I and II narcolepsy
 - Initiate clinical trial shortly after IH trial initiation
- Recent trial data suggest SDX has potential as a treatment option for Stimulant Use Disorder (SUD)
 - KP879 Phase 1 clinical trial data was compelling; scientific rationale still exists
 - Development program will be challenging and lengthy
 - Actively seeking partnership with government, academia and/or industry to advance
 - Engaged with top-tier firm to investigate and pursue various government grants/funding



Pipeline Expansion Strategy to Accelerate Value Creation

- Currently reviewing several earlier stage internal programs as potential lead candidates to add to the development pipeline
- External focus is primarily within the broad CNS/rare diseases space, with a particular focus on rare diseases or niche/specialty markets
- Actively seeking assets in Phase 2 stage or later, subject to our evaluation criteria, for in-licensing/acquisition
 - Assets need to fit within the framework of the business and current market dynamics

Due diligence on a host of assets takes time as we seek to:

- 1) Understand whether a potential molecule shows an efficacy signal for a specific indication
- 2) Understand the regulatory pathway (hurdles, time, cost, probability of success)
- 3) Understand commercial potential, competitive landscape, resources
- 4) Evaluate business structure and other dynamics that impact the transaction
- 5) Compare opportunities to assess best investment for capital allocation



AZSTARYS®

**D-Methylphenidate Prodrug Product
for the Treatment of ADHD**



ASTARYS® - U.S. Commercialization Moving Forward as Expected

- **Full national field team staffing in place; national rollout underway**
 - As of April 2022, the AZSTARYS field sales team will have doubled in size to 90 from 45 at year end 2021
 - Added approximately **700 new prescribers during the first 2 months of 2022**
 - Over 60 prescribers have written more than 30 prescriptions
 - Over **2,600 pharmacies** have dispensed AZSTARYS
 - **As of today, over 110 million commercial** lives have access to AZSTARYS
 - AZSTARYS has been added by more than 20 managed care organizations including **2 of the 3 largest PBM's**
- **AZSTARYS Commercial Launch is a Significant Opportunity for KemPharm**
 - License agreement with Commave, an affiliate of GPC, provides significant economic benefits to KemPharm tied to the commercialization of AZSTARYS
 - *Current growth trajectory makes the potential for earning sales milestones in 2022 attainable*

Source: (1) Estimates from Corium, Inc.



Financial Update



Q4 and FY 2021 Results; Financial Position is a Source of Strength

- Q4 2021 revenue of \$2.6M and FY 2021 revenue of \$28.7M, derived primarily from royalties and consulting service fees
 - Q4 2021 net loss (\$2.7M), or (\$0.08) per share, and FY 2021 net loss attributable to common stockholders of (\$62.9M), or (\$2.11) per share
 - Q4 2021 net operating loss was (\$2.8M), and FY 2021 net operating income was \$7.7M
 - Looking ahead, R&D expense will increase in FY 2022 with the start of the KP1077 development program
- Balance sheet details as of Dec. 31, 2021:
 - Cash, and cash equivalents and long-term investments was \$127.8M as of Dec 31, 2021
 - All debt was eliminated during 2021
 - \$50M share repurchase program in place through 2023
 - Available cash, cash equivalents and long-term investments extends cash runway beyond 2025

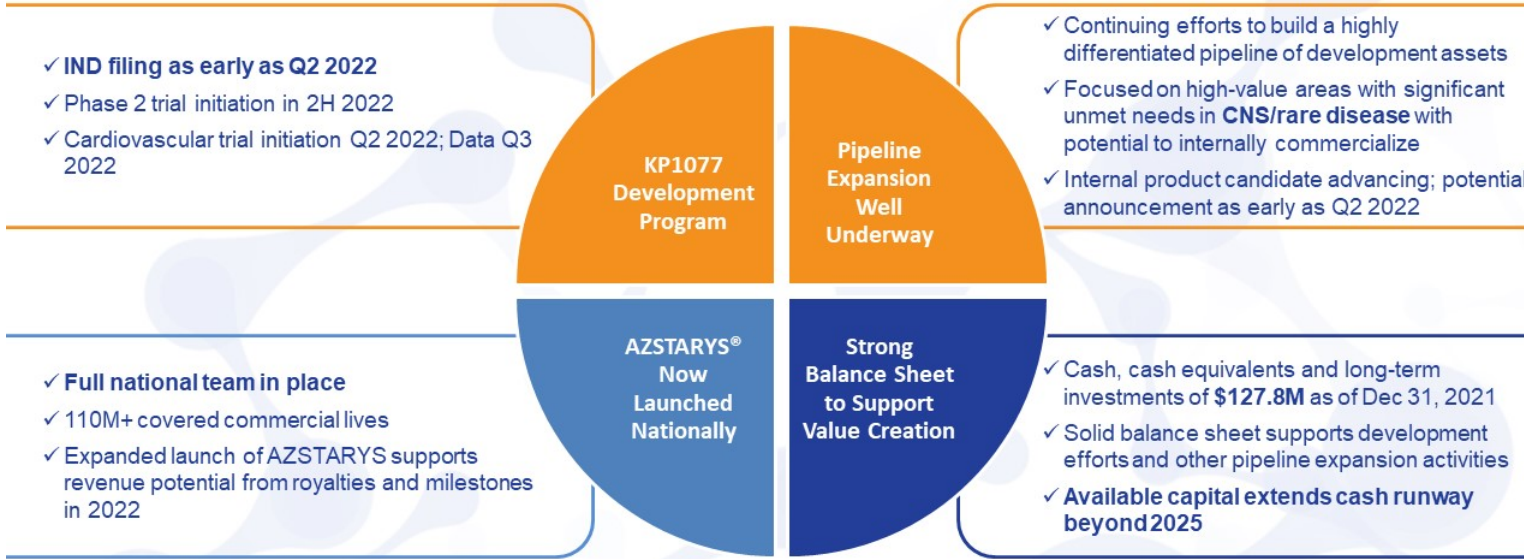


Upcoming Clinical, Reg and BD Milestones Create Potential Near-Term Value

| Milestone | Q1 2022 | Q2 2022 | Q3 2022 | Q4 2022 | Q1 2023 | Q2 2023 |
|---|---------|---------|---------|---------|---------|---------|
| KP1077 for IH | | | | | | |
| Type B meeting with FDA | ✓ | | | | | |
| IND filing/may proceed | | x | | | | |
| Phase 1 CV differentiation trial | | x | x | | | |
| Phase 2 trial | | | x | | | x |
| KP1077 for Narcolepsy | | | | | | |
| Type B meeting with FDA | | | x | | | |
| IND filing | | | | x | | |
| Phase 2/3 trial initiation | | | | x | | |
| KP879 | | | | | | |
| Final trial results | ✓ | | | | | |
| Additional clinical stage candidate(s) | | | | | | |
| | | | | | | |

Note: "X" denotes an event, **blue** box denotes activity timeframe

KemPharm: Development Activity Ramping Up in FY 2022





KemPharm ^{INC}

**Leveraging our LAT[®] Prodrug Technology
to Create Long-Term Value**

For additional information please
contact:
Jason Rando
jrando@tiberend.com

