

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): November 9, 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, par value \$0.0001 per share | 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 November 9, 2022, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its financial results for the third quarter ended September 30, 2022, 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, November 9, 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 November 9, 2022. |
| 99.2 | Presentation dated November 9, 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: November 9, 2022

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



KemPharm Reports Third Quarter 2022 Results

Conference Call and Live Audio Webcast with Slide Presentation Scheduled for Today, November 9, 2022, at 5:00 p.m. ET

- Significant activities underway for preparation of the arimoclocholol NDA resubmission
- Advancing key activities to initiate a Phase 2 clinical trial of KP1077 in IH by year-end 2022
- Total cash (cash, cash equivalents and long-term investments) of \$107.4M as of Sep 30, 2022; based on current operating forecast, cash runway extends into 2026

Celebration, FL – November 9, 2022 – KemPharm, Inc. (NasdaqGS: KMPH) (KemPharm, or the Company), a biotechnology company focused on the discovery, development and commercialization of novel treatments for rare central nervous system (CNS) and neurodegenerative diseases, lysosomal storage disorders and related treatment areas, today reported its financial results for the quarter ended September 30, 2022.

“During Q3, we made substantial progress with our two lead programs, arimoclocholol, our NDA-stage product candidate for Niemann-Pick Type C (NPC), an ultra-rare lysosomal disease, and KP1077, our product candidate based on our prodrug of d-methylphenidate, serdexmethylphenidate (SDX), which is intended for the treatment of two rare sleep disorders, idiopathic hypersomnia (IH) and narcolepsy,” stated Travis Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “For arimoclocholol, our team has made considerable progress characterizing the substantial data repository and generating a host of summary reports designed to present meaningful evidence of safety and efficacy as part of the NDA resubmission. Based on the recent completion of the 4-year open-label safety trial, the ongoing and constructive dialogue with the FDA and the new wealth of data generated since the CRL, we now anticipate resubmitting the updated NDA as early as Q3 2023. And, while no new or unanticipated issues related to resubmission have arisen, we believe the added time will be well-spent in preparation of an NDA filing with the highest likelihood of approval.”

Dr. Mickle continued, “For KP1077, the initial results we reported in October 2022 from the Phase 1 cardiovascular safety trial of SDX demonstrated the potential for ‘higher dose’ SDX to be safe and well-tolerated. We believe this could position KP1077 as an advancement in the treatment of IH, and we remain on track to initiate the Phase 2 clinical trial by the end of 2022.”

Dr. Mickle concluded, “We believe KemPharm is well-positioned with a strong investment thesis that we expect to be validated as the Company executes on a deep and differentiated development pipeline supported by a strong operational and financial foundation. This includes a cash runway that is forecasted to extend into 2026, which could be further bolstered by the potential to realize sales milestone and royalty revenue from AZSTARYS® as Corium executes its commercialization strategy. Altogether, we believe there are multiple catalysts for KemPharm during the remainder of 2022 and throughout 2023.”

Recent Business and Corporate Highlights:

- Continuing activities to bolster the arimoclomol New Drug Application (NDA) for resubmission to the U.S. Food and Drug Administration (FDA):
 - Working to amass and characterize a substantial data repository from a 4-year arimoclomol safety study, and pinpointing key elements to include in the NDA resubmission for arimoclomol based on new data generated since June 2021;
 - Ongoing collaborative dialogue and periodic meetings with the FDA intended to ensure an optimal NDA data package that demonstrates arimoclomol to be a safe and effective therapy for NPC, if approved; and
 - Currently anticipating resubmission of the updated NDA as early as Q3 2023, with plans to provide updated guidance if needed based on ongoing dialogue with the FDA as we seek to compile an optimal data package for resubmission.
 - Progress in advancing investigational candidate KP1077, an SDX-based product being developed as a treatment for IH and narcolepsy:
 - Completed Phase 1 cardiovascular safety clinical trial of SDX which confirmed the initial dosing strengths for the Phase 2 clinical trial of KP1077 in IH;
 - Data suggest that SDX can be safely dosed at levels higher than currently available methylphenidate-based products, which is expected to result in improved efficacy while avoiding the potential for greater cardiovascular safety risk; and
 - Preparing to initiate a Phase 2 clinical trial of KP1077 in patients with IH prior to year-end 2022 and a second trial in patients with narcolepsy in 2023.
 - Strong operational and financial foundation, including \$107.4 million in cash, cash equivalents and investments as of September 30, 2022:
 - Based on current operating forecast, cash runway is expected to continue into 2026; and
 - The potential to realize milestone and royalty revenue from AZSTARYS® as Corium executes its commercialization strategy could provide further capital flexibility and extend the operating cash runway.
-

Overview of Third Quarter 2022 Financial Results:

Net revenue for Q3 2022 was \$2.9 million, as compared to Q3 2021 net revenue of \$2.0 million. The period-over-period increase was primarily attributed to revenue from the arimoclomol Early Access Program (EAP) in France, partially offset by a decrease in revenue from consulting arrangements period over period.

Research and development expenses were \$5.4 million for Q3 2022, as compared to \$2.2 million in Q3 2021. The period-over-period increase was primarily driven by the KP1077 clinical development program, the arimoclomol program, increased depreciation/amortization related to the arimoclomol asset acquisition in the second quarter of 2022, and increased compensation costs, including non-cash stock-based compensation expense.

General and administrative expenses were \$4.0 million for Q3 2022, as compared to \$1.9 million in Q3 2021. The period-over-period increase was primarily driven by increased compensation costs, including non-cash stock-based compensation expense, as well as increased professional fees and depreciation/amortization related to the arimoclomol asset acquisition in the second quarter of 2022.

Net loss attributable to common stockholders for Q3 2022 was (\$6.6) million, or (\$0.19) per basic and diluted share, compared to a net loss attributable to common stockholders of (\$1.8) million, or (\$0.05) per basic and diluted share for the same period in 2021. Net loss for Q3 2022 was driven primarily by research and development expense of \$5.4 million, and general and administrative expense of \$4.0 million, partially offset by net revenues of \$2.9 million.

As of September 30, 2022, total cash, cash equivalents and investments were \$107.4 million, which was a decrease of \$7.1 million compared to \$114.5 million as of June 30, 2022, driven in part by increased third-party research and development costs related to the KP1077 clinical trial program, the arimoclomol program, other expenses, as well as investment of working capital related to the collection of accounts receivable due from French EAP reimbursements. Based on the Company's current operating forecast, existing cash, cash equivalents and investments are expected to be sufficient to continue operations into 2026.

As of September 30, 2022, total shares of common stock outstanding was 34,501,144 shares, and fully diluted common shares outstanding was 47,076,872 shares, which included 4,252,600 shares issuable upon exercise of warrants.

Conference Call Information:

KemPharm will host a conference call and live audio webcast with a slide presentation today at 5:00 p.m. ET, to discuss its corporate and financial results for the third quarter of 2022.

The audio webcast with slide presentation will be accessible via the Investor Relations section of the Company'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 November 9, 2022.

Additionally, interested participants and investors may access conference call by dialing either:

- (800) 225-9448 (U.S.)
- (203) 518-9708 (International)
- Conference ID: KMPHQ322

About KemPharm:

KemPharm is a biotechnology company focused on the discovery, development and commercialization of novel treatments for rare CNS and neurodegenerative diseases, lysosomal storage disorders and related treatment areas. KemPharm has a diverse product portfolio, combining a clinical-stage development pipeline with NDA-stage and commercial assets. The pipeline includes arimoclomol, an orally-delivered, first-in-class investigational product candidate for Niemann-Pick disease type C (NPC), and KP1077, which the Company is developing as a treatment for idiopathic hypersomnia (IH), a rare neurological sleep disorder, and narcolepsy. In addition, the U.S. Food and Drug Administration (FDA) has approved AZSTARYS®, a once-daily treatment for ADHD in patients age six years and older containing KemPharm's prodrug, serdexmethylphenidate (SDX), which is being commercialized by Corium, Inc. in the U.S. The FDA has also approved 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 product candidates visit www.kempharm.com or connect with us on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

Early access programs are made available by KemPharm, Inc. and its affiliates, and are subject to the Company's Early Access Program (EAP) policy as published on its website at www.kempharm.com. Participation in these programs is subject to the laws and regulations of each jurisdiction under which each respective program is operated. Eligibility for participation in any such program is at the discretion of the treating physician.

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 Investigational New Drug applications and NDA submissions, including the resubmission of the NDA for arimoclomol, communications with the FDA, the potential uses or benefits of arimoclomol, KP1077, SDX, or any other product candidates for any specific disease indication or at any dosage, the potential benefits of any of KemPharm's product candidates, the sufficiency of cash to fund operations, the potential for and timing of milestone and/or royalty revenues, our plans or ability to seek funding, 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, as updated by the Quarterly Report on Form 10-Q for the three months ended September 30, 2022, 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.

KemPharm Contacts:

[Tiberend Strategic Advisors, Inc.](#)
Jason Rando/Daniel Kontoh-Boateng
jrando@tiberend.com
dboateng@tiberend.com

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

| | Three months ended September 30, | | Nine months ended September 30, | |
|--|----------------------------------|------------|---------------------------------|-------------|
| | 2022 | 2021 | 2022 | 2021 |
| Revenue, net | \$ 2,874 | \$ 1,965 | \$ 8,139 | \$ 26,068 |
| Operating expenses: | | | | |
| Cost of revenue | 141 | 0 | 200 | 2,000 |
| Research and development | 5,385 | 2,239 | 13,262 | 7,352 |
| General and administrative | 3,974 | 1,948 | 10,266 | 6,145 |
| Acquired in-process research and development | — | — | 17,663 | — |
| Total operating expenses | 9,500 | 4,187 | 41,391 | 15,497 |
| (Loss) income from operations | (6,626) | (2,222) | (33,252) | 10,571 |
| Other (expense) income: | | | | |
| Loss on extinguishment of debt | — | — | — | (16,096) |
| Interest expense related to amortization of debt issuance costs and discount | — | — | — | (150) |
| Interest expense on principal | (124) | (6) | (165) | (221) |
| Fair value adjustment related to derivative and warrant liability | 22 | 332 | 295 | (92) |
| Interest and other (expense) income, net | 79 | 137 | (152) | 136 |
| Total other (expense) income | (23) | 463 | (22) | (16,423) |
| Loss before income taxes | (6,649) | (1,759) | (33,274) | (5,852) |
| Income tax benefit | 33 | — | 752 | — |
| Net loss | \$ (6,616) | \$ (1,759) | \$ (32,522) | \$ (5,852) |
| Deemed dividend | — | — | — | (54,342) |
| Net loss attributable to common stockholders | \$ (6,616) | \$ (1,759) | \$ (32,522) | \$ (60,194) |
| Basic and diluted net loss per share of common stock: | | | | |
| Net loss attributable to common stockholders | \$ (0.19) | \$ (0.05) | \$ (0.94) | \$ (2.16) |
| Weighted average number of shares of common stock outstanding: | | | | |
| Basic and diluted | 34,494,702 | 35,217,953 | 34,482,791 | 27,904,711 |

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

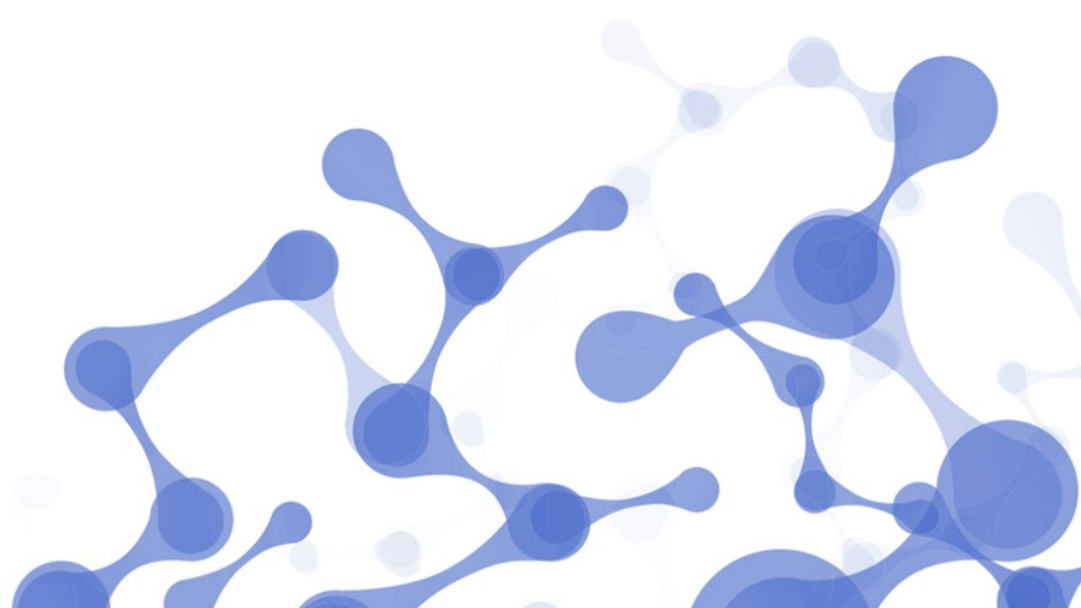
| | September 30, 2022 | December 31, 2021 |
|--|-----------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 70,059 | \$ 112,346 |
| Short-term investments | 5,832 | — |
| Accounts and other receivables | 6,583 | 1,528 |
| Prepaid expenses and other current assets | 2,659 | 1,182 |
| Total current assets | 85,133 | 115,056 |
| Inventories | 596 | — |
| Property and equipment, net | 852 | 884 |
| Operating lease right-of-use assets | 1,068 | 1,141 |
| Long-term investments | 31,463 | 15,422 |
| Other long-term assets | 439 | 438 |
| Total assets | \$ 119,551 | \$ 132,941 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 4,279 | \$ 3,038 |
| Current portion of operating lease liabilities | 474 | 356 |
| Current portion of discount and rebate liabilities | 2,825 | — |
| Other current liabilities | 853 | 836 |
| Total current liabilities | 8,431 | 4,230 |
| Line of credit payable | 12,800 | — |
| Derivative and warrant liability | 35 | 330 |
| Operating lease liabilities, less current portion | 956 | 1,232 |
| Discount and rebate liabilities, less current portion | 3,509 | — |
| Other long-term liabilities | 26 | 31 |
| Total liabilities | 25,757 | 5,823 |
| Commitments and contingencies (Note D) | | |
| Stockholders' equity: | | |
| Preferred stock: | | |
| Undesignated preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2022 or December 31, 2021 | — | — |
| Common stock, \$0.0001 par value, 250,000,000 shares authorized, 35,411,097 shares issued and 34,501,144 shares outstanding as of September 30, 2022; 35,325,801 shares issued and 35,005,640 shares outstanding as of December 31, 2021 | 3 | 4 |
| Additional paid-in capital | 400,677 | 396,957 |
| Treasury stock, at cost | (7,536) | (2,814) |
| Accumulated deficit | (299,551) | (267,029) |
| Accumulated other comprehensive income | 201 | — |
| Total stockholders' equity | 93,794 | 127,118 |
| Total liabilities and stockholders' equity | \$ 119,551 | \$ 132,941 |



KemPharm^{INC}

Q3 2022 Results Call

November 9, 2022



Trademarks herein are held by their respective owners.

Cautionary Note Regarding Presentation Information

This presentation 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 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 Investigational New Drug applications and NDA submissions, including the resubmission of the NDA for arimoclomol, communications with the FDA, the potential uses or benefits of arimoclomol, KP1077, SDX or any other product candidates for any specific disease indication or at any dosage, 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 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, as updated by the Quarterly Report on Form 10-Q for the three months and nine months ended September 30, 2022, 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 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.



Q3 2022 Results Call Agenda

1) Introduction

Travis Mickle, Ph.D.
President and Chief Executive Officer

2) Product Development Updates

Travis Mickle

3) Financial Update

R. LaDuane Clifton, CPA
Chief Financial Officer, Secretary & Treasurer

4) Question and Answer



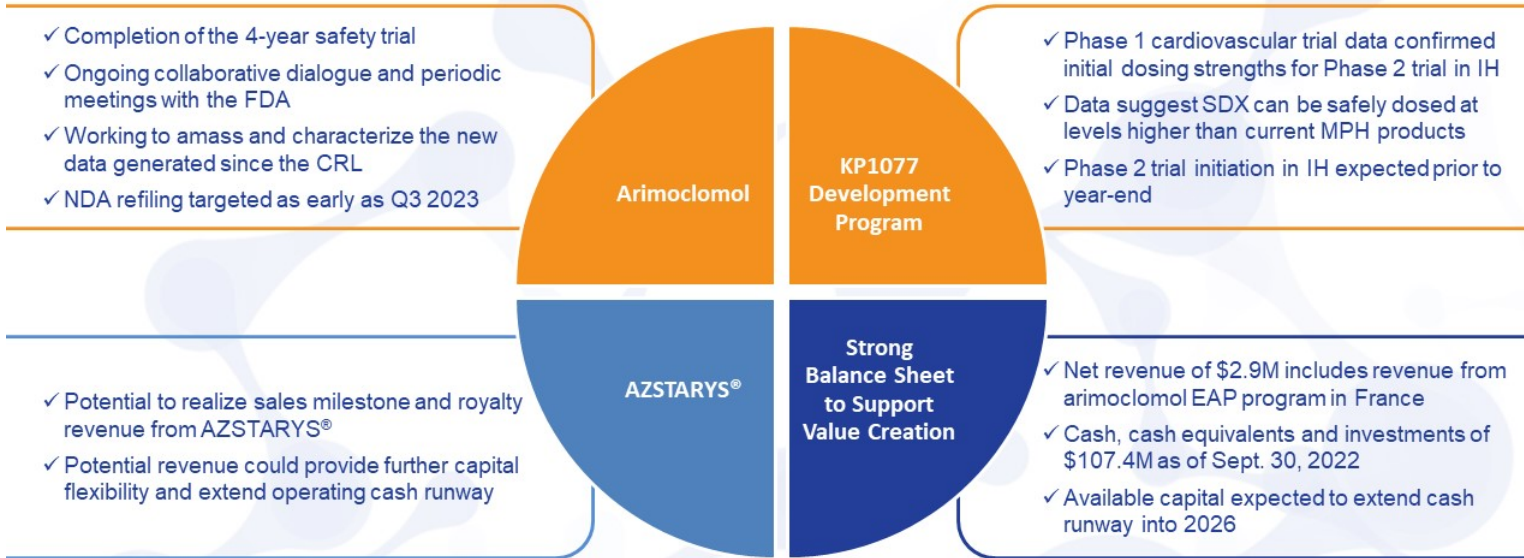
KEMPHARM VALUE PROPOSITION

Innovative biotech company with a proven regulatory track record targeting rare CNS, neurodegenerative and lysosomal storage diseases

Revenue-generating assets with significant commercial potential in areas of high unmet need

Strong balance sheet which is expected to fund operations and U.S. commercial build into 2026

KemPharm: Q3 2022 and Recent Highlights



Product Development Updates



Arimoclomol - Expanding Pipeline Targeting Rare Diseases

Aligns with strategy to build value through the development and commercialization of novel treatments for rare diseases

Niemann-Pick disease type C

- ✓ Ultra-rare progressive, disabling and fatal lysosomal storage disorder
- ✓ No approved treatments exist in the U.S. for NPC

Favorable Acquisition Terms

- ✓ "Capital efficient" financial structure with potential for positive cash flow and no shareholder dilution



High Upside Opportunity

- ✓ NDA-stage investigational drug candidate
- ✓ KemPharm has expertise in NDA resubmissions following CRLs

Early Access Programs

- ✓ Available to NPC patients in the U.S., France, Germany and other European countries
- ✓ French EAP expected to generate annual gross revenue of ~\$12M



Path to Resubmission and Approval Progressing

KemPharm has significant experience with challenging regulatory situations, including two FDA product approvals that followed initial CRLs

Recent Activities

- Continuing to have an ongoing collaborative dialogue and periodic meetings with the FDA
 - ✓ Intended to ensure an optimal NDA data package that addresses all issues in the CRL
- Advancing activities to bolster arimoclomol NDA with confirmatory evidence for resubmission to the FDA
 - ✓ Working to analyze and process the new data generated since the CRL
 - ✓ This includes data obtained from a 4-year arimoclomol safety study and safety data from other clinical trials with arimoclomol

Regulatory Outlook

- Throughout this process, no new issues or concerns have been raised by the FDA
 - No new efficacy trial has been proposed by FDA
- We believe there is a viable pathway to enable a successful NDA resubmission and subsequent approval for arimoclomol in NPC
 - ✓ Path may include, if necessary, additional non-clinical or clinical studies, a Federal Dispute Resolution Request (FDRR) and/or an advisory committee (ad com) requested by either FDA or KemPharm

KemPharm expects to resubmit the NDA for arimoclomol in NPC as early as Q3 2023

KP1077 – Product Candidate Overview

KemPharm is advancing KP1077 as a potential therapeutic treatment for Idiopathic Hypersomnia (IH)

Serdexmethylphenidate

- ✓ 100% SDX with multiple dosing options
- ✓ SDX has already been designated C-IV by DEA

Regulatory & IP Advantages

- ✓ Eligible for Fast-Track, Orphan Drug and Breakthrough Therapy designation
- ✓ Solid IP through 2037 and potentially beyond



Dosing Addresses Symptoms

- ✓ Dosed either 1x daily at bedtime or 2x daily at bedtime and at waking
- ✓ Potential to address primary IH symptoms: sleep inertia and brain fog

Improved Safety & Tolerability

- ✓ Greater tolerability and lower cardiovascular effects could allow for higher, more effective dosing (i.e. greater efficacy)
- ✓ No DDI potential with hormonal contraceptives; antidepressants



KP1077 – Multiple Clinical Programs Targeting Rare Sleep Indications

KP1077 Represents a Potential “Portfolio in a Pill” Opportunity

Idiopathic Hypersomnia

- Lead KP1077 indication
- Investigational New Drug (IND) application cleared by FDA
- Initiation of Phase 2 clinical trial anticipated prior to year-end 2022
- Interim data from Phase 2 clinical trial expected by mid-year 2023
- Top-line data available by EOY 2023

Narcolepsy

- Second KP1077 indication would allow KemPharm to address two rare sleep indications that are underserved by currently available medications
- Initiate narcolepsy Phase 3 Trial post IH Phase 2 results
 - Leverage key data points from IH program to expedite narcolepsy development



Financial Update and Upcoming Milestones



Financial Position is a Source of Strength

Q3 2022 Income Statement Details:

- Net revenue of \$2.9M, primarily from the arimoclomol EAP program in France
- Q3 2022 net loss attributable to common stockholders of (\$6.6M), or (\$0.19) per basic and diluted share, driven primarily by R&D expense of \$5.4M, and general and administrative expense of \$4.0M
 - Partially offset by net revenues of \$2.9 million

Balance Sheet Details as of Sept. 30, 2022:

- Cash, cash equivalents and investments were \$107.4M, a decrease of \$7.1M compared to Q2 2022
 - Driven in part by increased third-party research and development costs related to the KP1077 clinical trial program, the arimoclomol program, other expenses, as well as investment of working capital related to the collection of accounts receivable due from French EAP reimbursements
- Available cash, cash equivalents and investments expected to extend cash runway into 2026



KemPharm: Multiple Growth Catalysts

- ✓ Potential to re-file NDA as early as Q3 2023
- ✓ Anticipated ongoing quarterly revenue from EAP program in France

Arimocloamol

KP1077

- ✓ Phase 2 trial initiation in IH by the end of 2022
- ✓ Interim Phase 2 IH data expected by mid-2023
- ✓ Phase 3 trial in narcolepsy to initiate following IH Phase 2 trial results

- ✓ Potential to realize sales milestone and royalty revenue from AZSTARYS, providing further capital flexibility and extending operating cash runway

AZSTARYS®

Strong
Balance Sheet
to Support
Value Creation

- ✓ Solid balance sheet supports development efforts and other pipeline expansion activities
- ✓ Available capital extends cash runway into 2026





KemPharm^{INC}

**Addressing Rare CNS, Neurodegenerative
and Lysosomal Storage Diseases**

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

