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 7, 2022**

CARA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36279**	**75-3175693**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
4 Stamford Plaza **107 Elm Street, 9th Floor** **Stamford, Connecticut** (Address of principal executive offices)		**06902** (Zip Code)

Registrant's telephone number, including area code **(203) 406-3700**

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 Instruction A.2.):

☐ 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**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	CARA	The Nasdaq Stock Market LLC

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 7.01. Regulation FD Disclosure.

On November 7, 2022, Cara Therapeutics, Inc. (the "Company") made available an updated corporate presentation, which can be found on the Company's website (the "Corporate Presentation"). The Corporate Presentation is furnished as Exhibit 99.1 and incorporated by reference in this Item 7.01.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any of the Company's filings with the Securities and Exchange Commission ("SEC") under the Exchange Act or the Securities Act of 1933, as amended, (the "Securities Act") whether made before or after the date hereof, regardless of any general incorporation language in such a filing. The information shall not be deemed incorporated by reference into any other filing with the SEC made by the Company, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Corporate Presentation, dated November 7, 2022
104	Cover page interactive data file (formatted as Inline XBRL)

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 hereunto duly authorized.

CARA THERAPEUTICS, INC.

By: /s/ CHRISTOPHER POSNER
Christopher Posner
Chief Executive Officer

Date: November 7, 2022

Exhibit 99.1

Cara Therapeutics

NOVEMBER 2022

Forward Looking Statements

Statements contained in this presentation regarding matters that are not historical facts are "forward-looking state the meaning of the Private Securities Litigation Reform Act of 1995. Examples of these forward-looking state statements concerning the Company's ability to successfully commercialize KORSUVA injection and Kapruvia, f and profit share from sales of KORSUVA and Kapruvia, planned future regulatory submissions and potential fut approvals, the performance of the Company's commercial partners, including CSL Vifor, expected timing of enrollment and data readouts from the Company's planned and ongoing clinical trials, the potential results of o trials, timing of future regulatory and development milestones for the Company's product candidates, the po Company's product candidates to be alternatives in the therapeutic areas investigated, including NP, and the po difelikefalin to address additional pruritic indications, the size and growth of the potential markets for pruritus man the Company's expected cash reach. Because such statements are subject to risks and uncertainties, actual res materially from those expressed or implied by such forward-looking statements. These risks and uncertainties ir risks inherent in the launch of new products, including that our commercial partners, including CSL Vifor, may r expected, risks inherent in the clinical and regulatory development of pharmaceutical products, and the risks de fully in Cara Therapeutics' filings with the Securities and Exchange Commission, including the "Risk Factors" Company's Annual Report on Form 10-K for the year ending December 31, 2021 and its other documents subs with or furnished to the Securities and Exchange Commission, including its Form 10-Q for the quarter ended S 2022. All forward-looking statements contained in this presentation speak only as of the date on which they wer Therapeutics undertakes no obligation to update such statements to reflect events that occur or circumstances the date on which they were made, except as required by law.


OUR MISSION:
Transform the way pruritus is treated to bring quality to the lives of those who suffer.

Millions of US patients could benefit from a chron pruritus therapy

		Estimated US Pruritis Po
SYSTEMIC	HD-Dependent Chronic Kidney Disease (CKD)[1-2]	200
	Non-Dialysis Dependent CKD (Stage 4-5)[3-7]	300
	Chronic Liver Disease[8-12]	3M
DERMATOLOGICAL	Atopic Dermatitis[13-15]	12
NEUROLOGICAL	Notalgia Paresthetica[16-19]	>65

1..National Institute of Diabetes and Digestive and Kidney Diseases. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease. 2. Pisoni et al. Pruritus in haemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study (DOPP Nephrology Dialysis Transplantation (2006); 21(12): 3495-3505. 3. Centers for Disease Control and Prevention https://nccd.cdc.gov/ckd/detail.aspx?Qnum=Q372. 4. DataMonitor 5. States Renal Data System https://adr.usrds.org/2020/chronic-kidney-disease/1-ckd-in-the-general-population. 6. Wong SJY et al. Decisions about Renal Replacement Therapy in Patients with Advanced Kidney Disease in the US Department of Veterans Affairs, 2000–2011. Clin Journal of Am Soc Neprol. 2016. 11(10): 1825-1833. 7. Sukul N et al. Pruritus and patient reporte outcomes in non-dialysis CKD. Clin J Am Soc Neprhol 2019. 673-681. 8.Centers for Disease Control and Prevention https://www.cdc.gov/nchs/fastats/liver-disease.htm 9. Odea S et al. Prevalence of pruritus in patients with chronic liver disease: A multicenter study. Hepatology Research. 2018. 28(3): E252-E262. 10. Fujino H et al. Pruritus in patients with chronic liver disease and serum autotaxin levels in patients with primary biliary cholangitis. BMC Gastroenterology. 2019. 19:169. 11. Yoshikawa et al. Pruritus is common in patients with chronic liver disease and is improved by nalfurafine hydrochloride. Scientific Reports. 2021. 11:3015. 12. Data on file. 13. National Eczema Assocaition. https://nationaleczema.org/eczema/types-of-eczema/atopic-dermatitis/ 14. DRG Analysis. 15. Mollanazar NK, Smith PK, Yosipovitch G. Mediators of chronic pruritus in atopic dermatitis: getting the itch out? Clin Rev Allergy Immunol. (2016) 51:263–92. 16. US Census Bureau 2020 population projection; 17. Pereira P. et al., Acta DV 2018 ; 98:82-88; 18. Mollanazar N.K. et al., Acta Clin Croat 2018; 57:721-725e.; 19 Syneos market research and Apollo claims database

Cara is well positioned to seize the opportunity ar drive significant immediate and future growth

KORSUVA Injection is poised for rapid uptake

KORSUVA®
(difelikefalin) Injection
65 mcg/1.3 mL (50 mcg/mL)

- FIRST-AND-ONLY PRODUCT APPROVED FOR CI
- STRONG COMMERCIAL POSITIONING & PARTNI
- FIRST INNOVATIVE PRODUCT TO RECEIVE TDA

 Korsuva is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD). Limitations of Use Korsuva has not been studied in patients on peritoneal dialysis and is not recommended for use in this population

KORSUVA Injection addresses significant unmet n
in US CKD-aP hemodialysis market

~500K

Patients on hemodialysis[1-2]

40%

With moderate-severe pruritus[2]

~200

Addressable Mar

1. National Institute of Diabetes and Digestive and Kidney Diseases. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.
2. URSDS. https://adr.usrds.org/2021/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities
3. Pisoni et al. Pruritus in haemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Nephrology Dialysis Transplantation (2006); 21(12): 3495-3505.

Concentrated dialysis market dynamics provides potential for rapid uptake

2 Key Providers

- **Fresenius Medical Care and DaVita have a combined market share of ~75%[1]**

FRESENIUS MEDICAL CARE

DaVita Kidney

1 Major Payer

- **Medicare covers ~80% of CKD-HD patients[2]**
- **2nd drug in TDAPA**
  - 1st drug Parsabiv - $1.4B revenue in 3-yr period[3]

Medicare

1. https://healthcareappraisers.com/2020-outlook-dialysis-clinics-and-esrd/
2. https://adr.usrds.org/2020/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd
3. Amgen Annual Report 2018, 2019, 2020

Partnership with CSL Vifor can maximize launch p

CARA™ THERAPEUTICS

CSL Vifor

- Leading commercial nephrology organization with turnkey infrastructure, including 100+ sales FTEs
- Strong relationships with US nephrology offices and dialysis centers, including joint-venture with Fresenius Medical Care*
- Contractual economics bring near term profitability for KORSUVA Injection

 *Vifor has contracted the sales force of Fresenius Renal Pharmaceuticals, a division of Fresenius Medical Care North America, to complement its sales force in selling into Fresenius clinics in the U.S. CSL Limited completed its acquisition of Vifor Pharma AG in August 2022.

KORSUVA injection U.S. launch commenced in Ap 2022 and is progressing well

KORSUVA injection is available to order at all dialysis organizations nationwide

Healthcare Providers and Patients are being educated and activated

Product reimbursement via TDAPA is in place

U.S. KORSUVA Injection Sales

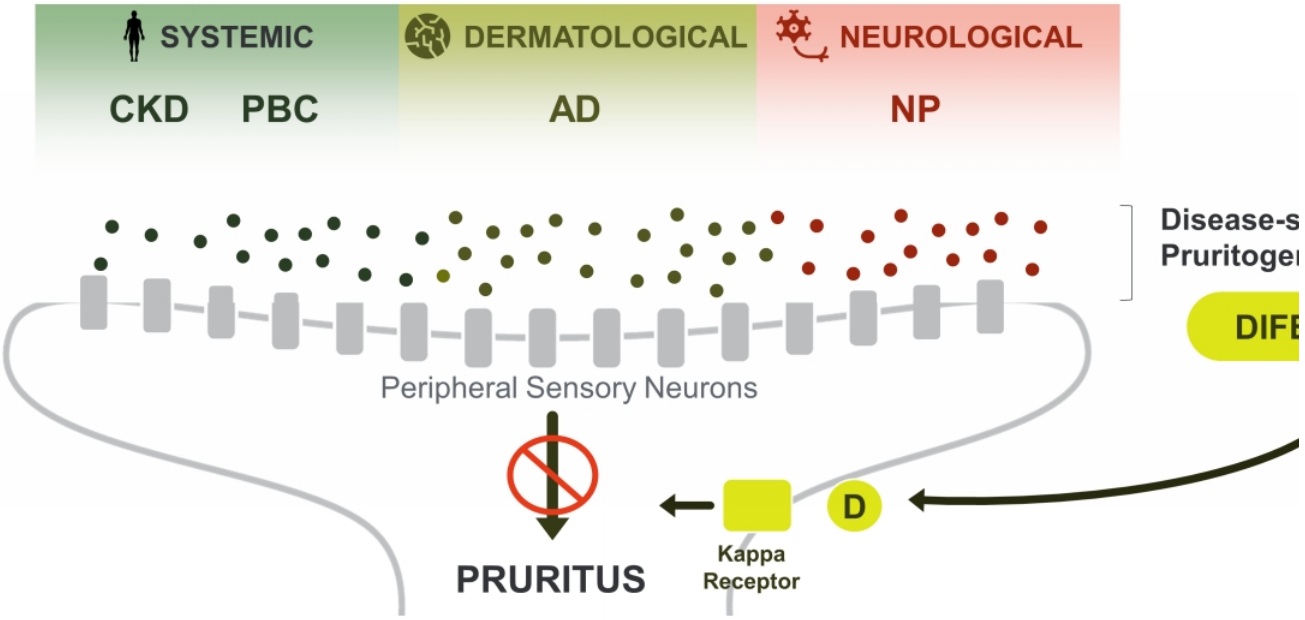
KORSUVA®
(difelikefalin) Injection
65 mcg/1.3 mL (50 mcg/mL)

Q2 2022	Q3 2022
KORSUVA Net Sales*: $16.8 million	KORSUVA Net Sales*: $16.2 mil
Profit-Sharing Revenue**: $8.0 million	Profit-Sharing Revenue**: $7.4 m
Vial Shipments***: 1,812	Vial Shipments***: 184,440

* KORSUVA Net Sales: shipment from Vifor to wholesaler
** Profit-Sharing Revenue: Net Revenues – COGS - % Sales & Marketing Fee
Profit Split: 50:50 Cara/Fresenius in Fresenius clinics; 60:40 Cara/Fresenius in non-Fresenius clinics
***Vial Shipments: Shipment from wholesaler to clinics

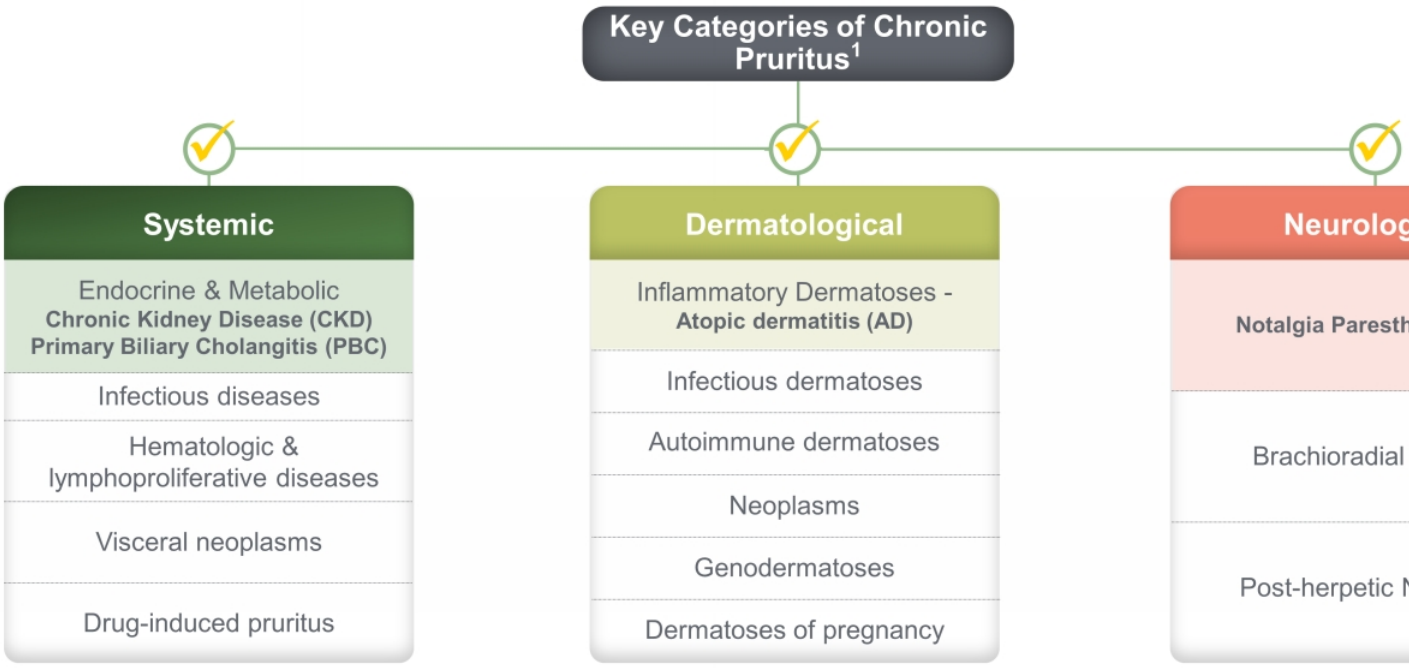
Difelikefalin MOA has potentially broad applicatio

Difelikefalin blocks itch response agnostic of itch trigger



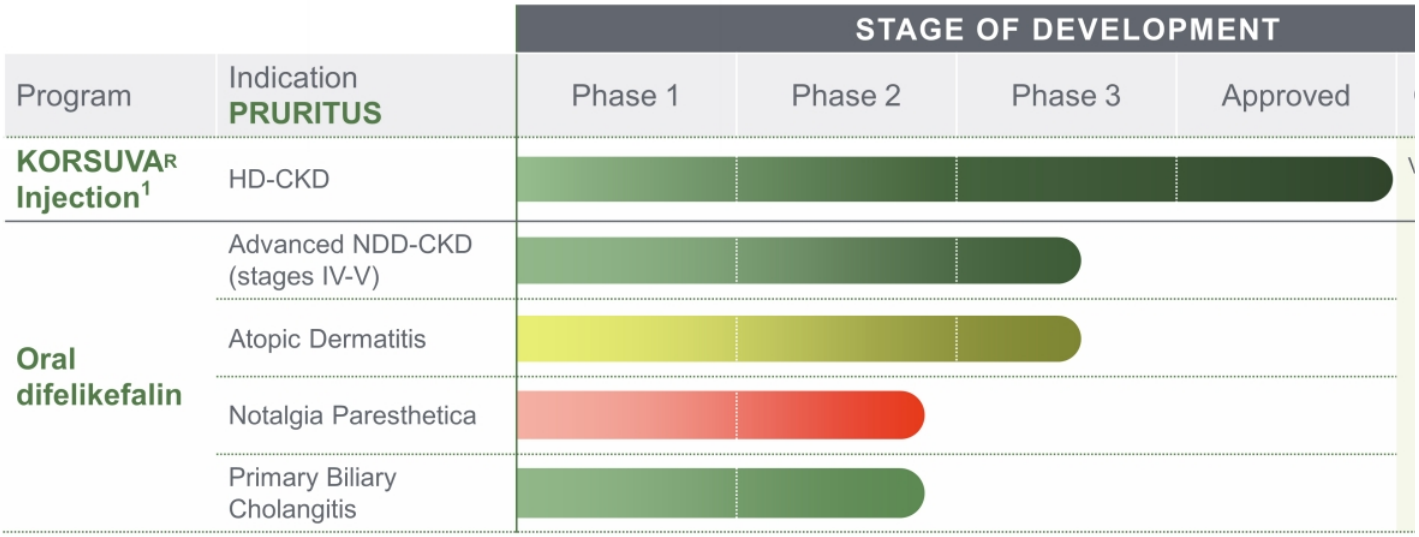
 | Adapted from Pflugers Arch . 2013 December ; 465(12): doi:10.1007/s00424-013-1284-2.

Oral difelikefalin has potential for long-term growt



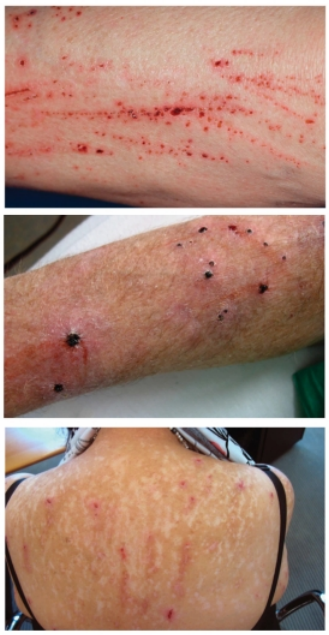
1. Matterne U. et al. Prevalence, correlates and characteristics of chronic pruritus: a population-based crosssectional study. Acta Derm Venereol. 2011;91(6):674-9.2. Matterne U et al. Incidence and determinants of chronic pruritus: a population-based cohort study. Acta Derm Venereol. 2013;93(5):532-7. 3. Adapted from: Stander S. et al. Clinical classification of itch: a position paper of the international forum for the study of itch. Acta Derm Venereol 2007. 87: 291-294.

Advancing our late-stage pipeline in multiple indications



1. Approved in the EU and UK with the tradename Kapruvia®. 2. Commercialization rights to difelikefalin in defined indications - Japan: Maruishi Pharmaceutical Co, LTD; South Korea: Chong Kun Dang Pharmaceuticals. 3. Vifor Fresenius Medical Care Renal Pharma (VFMCRP) has commercial rights under a profit-share arrangement in the US and a royalty arrangement ex-US.
HD-CKD: Hemodialysis Chronic Kidney Disease; NDD-CKD: Non-Dialysis Dependent Chronic Kidney Disease

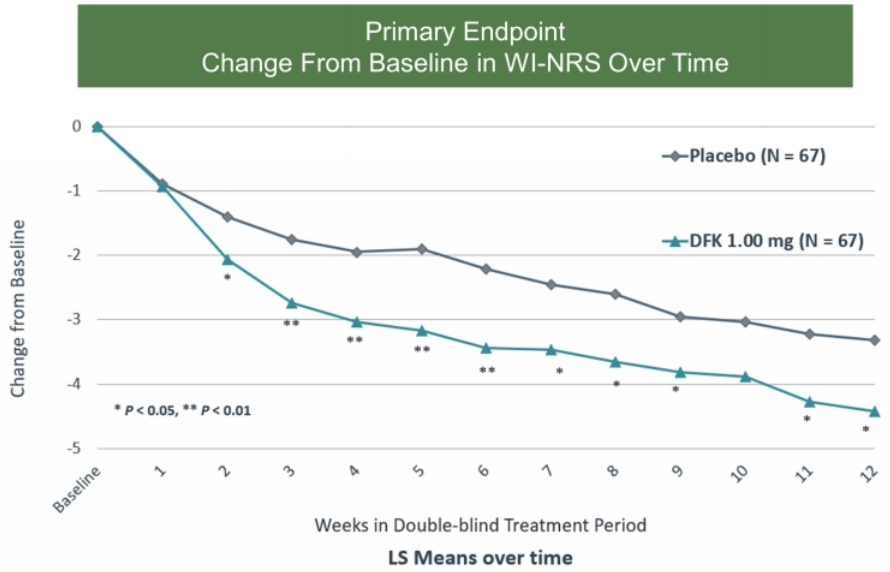
Oral difelikefalin: expanding reach in non-dialysis CKD market



- **Pruritis control is a significant unmet need among non CKD patients[1]**
- **There are no FDA-approved therapies and current anti- approaches are inadequate[1]**
- **Approximately 1.2 million US patients have advanced (non-dialysis CKD[2-5]**
- **~30% advanced non-dialysis CKD patients experience to severe pruritus[6]**

1. Makar M et al. Chronic kidney disease associated pruritus: a review. Kidney Blood Press Res 2021. 46:659-669. 2. Centers for Disease Control and Prevention https://nccd.cdc.gov/ckd/detail.aspx?Qnum=Q372. 3. DataMonitor 4. States Renal Data System https://adr.usrds.org/2020/chronic-kidney-disease/1-ckd-in-the-general-population. 5. Wong SJY et al. Decisions about Renal Replacement Therapy in Patients with Advanced Kidney Disease in the US Department of Veterans Affairs, 2000–2011. Clin Journal of Am Soc Neprol. 2016. 11(10): 1825-1833. 6. Sukul N et al. Pruritus and patient reported outcomes in non-dialysis CKD. Clin J Am Soc Neprhol 2019. 673-681. 7. Mettang T and Kremer AE. Uremic Pruritus. Kidney International. 2015. 87:685-691

Phase 2 data provides path forward into Phase 3 NDD-CKD

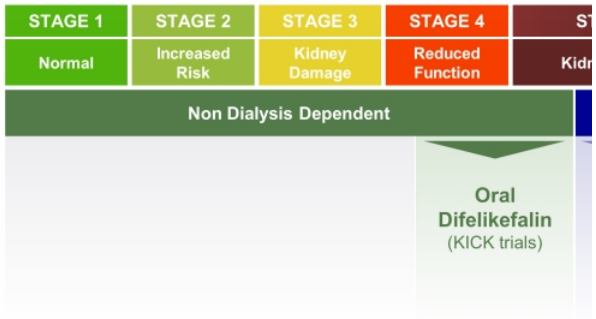


- ✓ **Significant difference achieve 1mg oral difelikefalin and plac NRS score at Week 12**
- ✓ **Generally well-tolerated with s profile consistent with clinica development program**
- ✓ **Phase 2 findings and EOP2 di with FDA established dose an population in Advanced CKD trial**

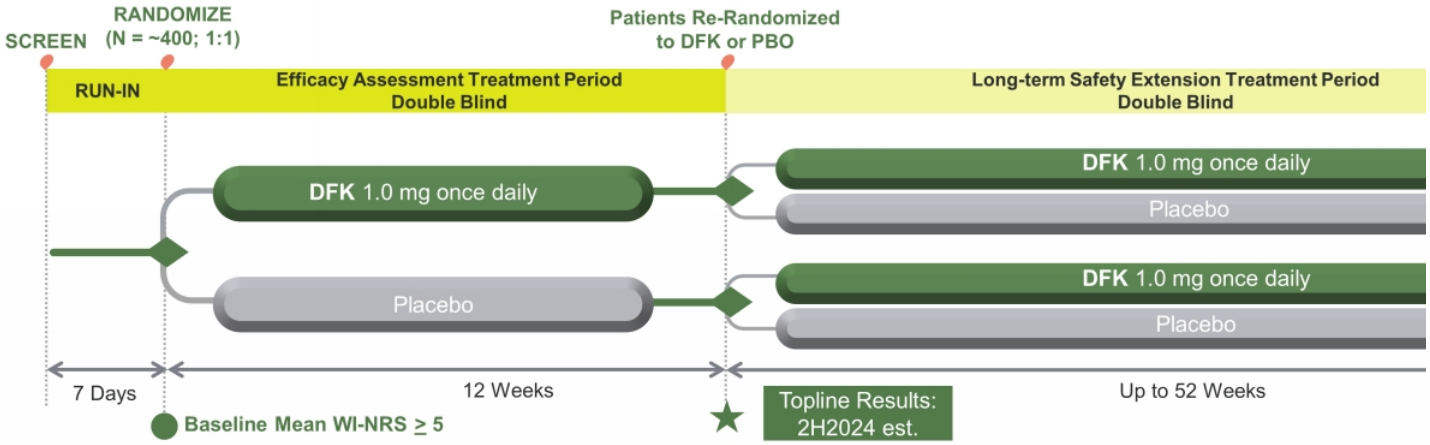
KICK 1 & KICK 2: Patient Population

STUDY PATIENT POPULATION

- Adults with advanced stage 4 and 5 CKD
- Chronic Pruritus for at least 6 months prior to screening
- Moderate to Severe Pruritus at Baseline (WI-NRS ≥ 5)
- Allowed to be on stable treatment for itch including antihistamines and gabapentinoids



KICK 1 & KICK 2: Study Design



PRIMARY ENDPOINT

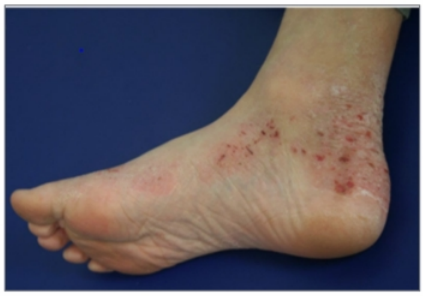
- **% of subjects with ≥4-point improvement from baseline in WI-NRS score at Week 12**

ADDITIONAL ENDPOINTS

- Quality of life including sleep
- Safety assessments

 KICK1 US sites only, KICK 2 US and ex-US sites

Oral difelikefalin: potential to address significant need for an oral antipruritic in atopic dermatitis (A



Pruritus is a hallmark of AD, often called "the itch that rashes"[1]

Itch is considered the most burdensome AD symptom patients[2], strongly and negatively impacts quality of li

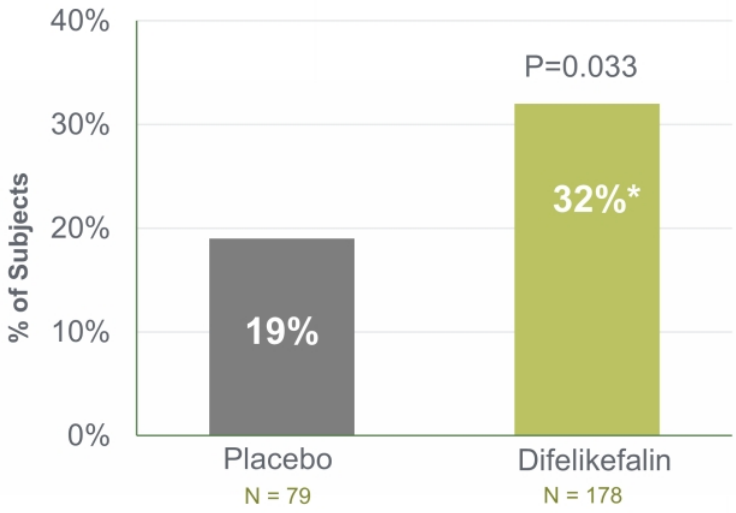
~12M diagnosed patients that experience chronic pru

Targeting pruritus in AD remains unmet need

1. Correale CE et al. Atopic dermatitis: a review of diagnosis and treatment. Am Fam Physician. 1999. 60(4):1191-1198 2. Silverberg JI et al. Patient burden and quality of life in atopic dermatitis in US adults. Annals of Allergy, Asthma, and Immunology (2018). 121(3): 340-347 3. Legat FJ. Itch in atopic dermatitis – what is new? Front Med (Lausanne) 2021. 8:644760. 4. National Eczema Assocaition. https://nationaleczema.org/eczema/types-of-eczema/atopic-dermatitis/ 5. DRG Analysis. 6. Mollanazar NK, Smith PK, Yosipovitch G. Mediators of chronic pruritus in atopic dermatitis: getting the itch out? *Clin Rev Allergy Immunol.* (2016) 51:263–92. 7. Lipman et al. Current clinical options for the management of itch in atopic dermatitis. Clin Cosmet Investig Dermatol. 2021. 14:959-969 8. Kapur S et al. Atopic dermatitis. Allergy Asthma and Clin Immunol. 2018. 14(Suppl2):52.

KARE STUDY: Phase 2 data in Atopic Dermatitis (

Population: Mild to Moderate AD (BSA <10)
4-point Responder Analysis at Week 12



- All doses performed similarly (.25mg, .50mg, 1.0mg) versus PBO

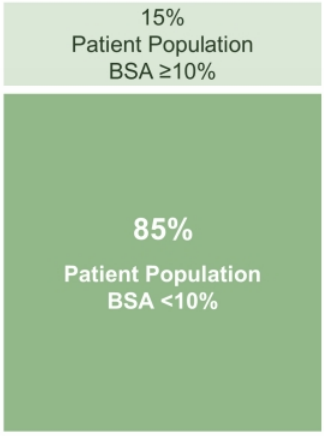
- ✓ **Anti-pruritic effect started at we was sustained through week 12**
- ✓ **Statistical significance achieved registration endpoint (4-point re in mild-to-moderate AD populati**
- ✓ **The drug was generally well tole**

KIND 1 & KIND 2: Patient Population

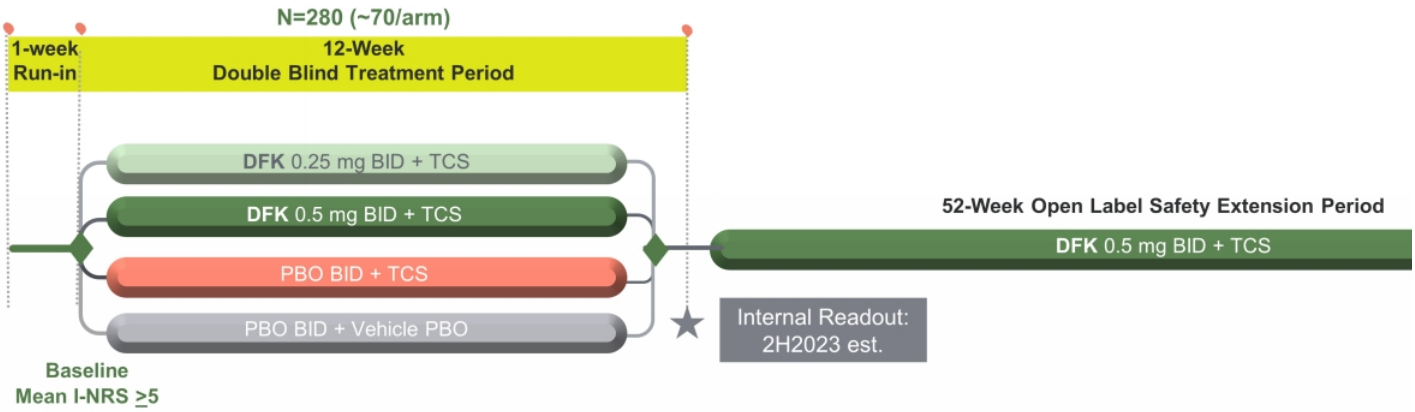
STUDY PATIENT POPULATION

- Adults with AD-related pruritus not adequately controlled by topical therapy alone
- Chronic AD-related Pruritus ≥6 weeks
- Moderate to Severe Pruritus at Baseline (I-NRS ≥ 5)
- Mild to severe Atopic Dermatitis:
  - IGA ≥ 2, BSA ≤20%
- Patients need to be washed out of any medication that may impact itch and/or AD prior to screening
- Stratification to BSA <10% and ≥10%

Target Enrollment



KIND 1 Part A: Study Design



CRITERIA

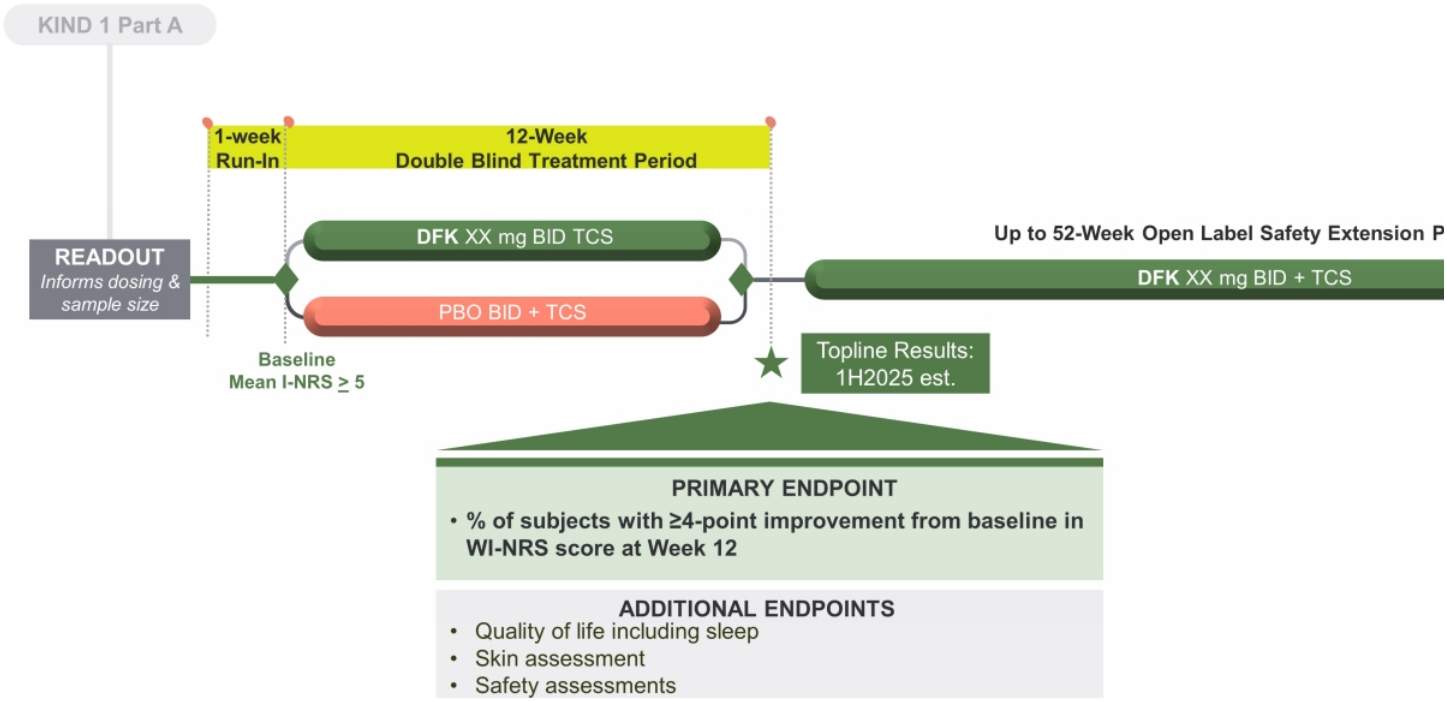
- % of subjects with ≥4-point improvement from baseline in WI-NRS score at Week 12
- Safety assessments

INFORMATION

- Dose
- Sample size

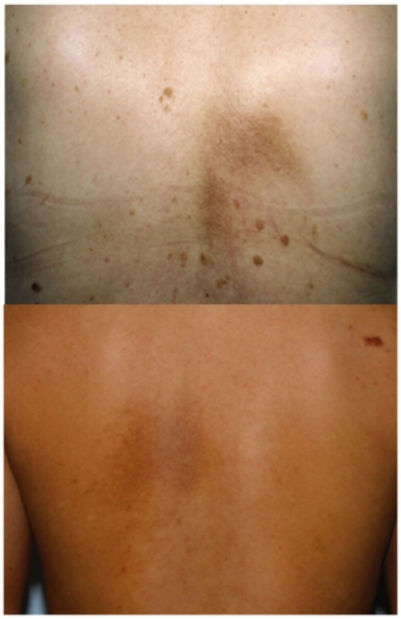
 KIND 1 Part A will include sites in North America only

KIND 1 Part B & KIND 2: Study Design



 | *KIND 1 Part B will include sites in North America only, while KIND 2 will include sites in North America and outside of North America*

Oral difelikefalin: potential to address significant need in Notalgia Paresthetica (NP)



NP is a sensory neuropathic syndrome characterized chronic pruritus[3]

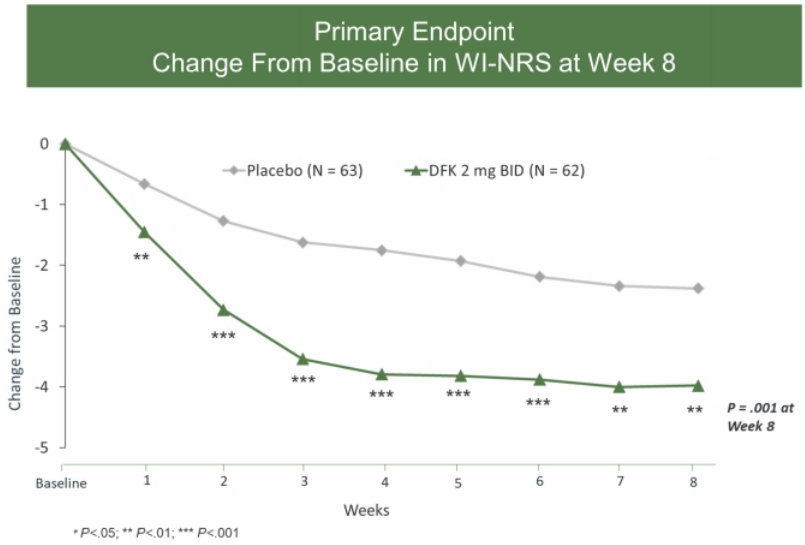
Pruritus is burdensome and impairs quality of life[1]

Estimated >650K patients currently treated for NP[2-5]

No FDA-approved treatments; off label treatments are either ineffective or have tolerability issues[1]

1. Howard M et al. Notalgia paresthetica: a review for dermatologists. Int J of Derm. 2017. 388-392. 2. US Census Bureau 2020 population projection; 3. Pereira P. et al., Acta DV 2018 ; 98:82-88; 4. Mollanazar N.K. et al., Acta Clin Croat 2018; 57:721-725; 5. Syneos Health qualitative primary research of US dermatologists, Feb 2022; 5. Syneos market research and Apollo claims database

Encouraging Phase 2 Data in First Well Controlled NP Study



- ✓ **Significant difference achieved b 2 mg BID oral difelikefalin and pl in WI-NRS score at Week 8**
- ✓ **Rapid onset of action within Wee sustained response through Wee**
- ✓ **Significantly greater proportion patients on difelikefalin with ≥ 4- improvement starting Week 2**
- ✓ **Generally well-tolerated with saf profile consistent with other clin development programs**

LS Means from MMRM with terms for treatment, week, treatment by week interaction, and baseline WI-NRS score
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption

Strong financial foundation to advance pipeline, e long-term growth

Cash runway into 1st half 2024

- This guidance assumes a level of Korsuva profit share revenue consistent with Q3 '22 actual

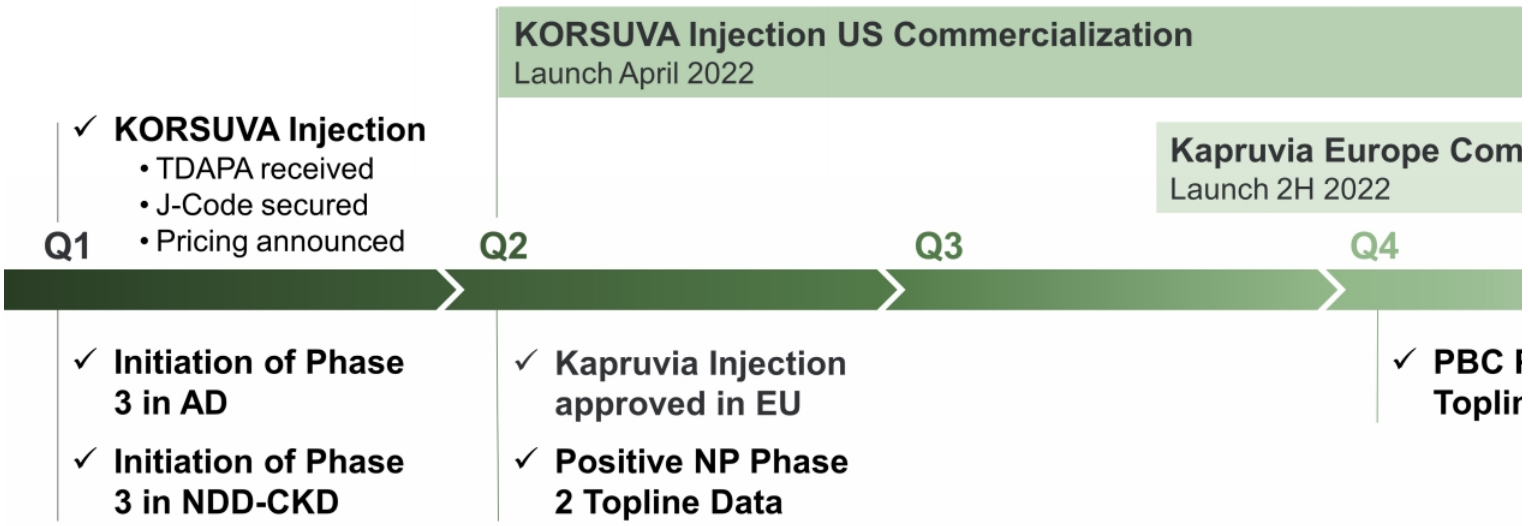
$180M cash position September 30, 2022

- 54M shares outstanding and no debt
- We do not expect to incur commercial costs related to KORSUVA Injec or Kapruvia

Continued pipeline growth

- We have the resources to continue development of the oral difelikefalin platforms

2022 Milestones and Potential Future Value Cataly Drive Long-term Growth



THANK YOU