
**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 10, 2020

Keros Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction
of incorporation)

001-39264
(Commission
File Number)

81-1173868
(I.R.S. Employer
Identification No.)

99 Hayden Avenue, Suite 120, Building E
Lexington, Massachusetts
(Address of principal executive offices)

02421
(Zip Code)

Registrant's telephone number, including area code: (617) 314-6297

Not applicable

(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:

- 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, \$0.0001 par value per share	KROS	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 2.02 Results of Operations and Financial Condition.

On November 10, 2020, Keros Therapeutics, Inc. (the "Company") issued a press release announcing its recent business highlights and financial results for the quarter ended September 30, 2020. A copy of the press release is furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section. The information contained in this Item 2.02 and in the accompanying exhibit is not incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure.

On November 10, 2020, the Company updated its corporate presentation for use in meetings with investors, analysts and others. The presentation is available through the Company's website and a copy is attached as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibit 99.2 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section. The information contained in this Item 7.01 and in the accompanying exhibit is not incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit

No.	Description
99.1	Press Release dated November 10, 2020.
99.2	Corporate Presentation dated November 2020.

Keros Therapeutics Reports Recent Business Highlights and Third Quarter 2020 Financial Results

Lexington, Massachusetts – November 10, 2020 – Keros Therapeutics, Inc. (“Keros” or the “Company”) (Nasdaq: KROS), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel treatments for patients suffering from hematological and musculoskeletal disorders with high unmet medical need, today provided a business update and reported financial results for the third quarter of 2020.

“We are very pleased to reach the significant milestone of dosing the first patients in our Phase 2 clinical trial of KER-050. The initiation of this trial is a tremendous accomplishment for Keros and moves us closer to proof-of-concept by potentially demonstrating therapeutic benefit for patients with myelodysplastic syndromes (“MDS”),” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer. “This Phase 2 clinical trial, along with the completion of our expanded Phase 1 clinical trial of KER-047, positions us to potentially have multiple ongoing Phase 2 clinical trials in 2021. Additionally, by regaining the rights to development programs in metabolic diseases and continuing rapid development of KER-012, Keros continues to further expand its already deep pipeline.”

Recent Corporate Highlights:

- **Return of worldwide rights to development programs in metabolic diseases:** On October 26, 2020, Keros announced that it received notice from Novo Nordisk A/S (“Novo Nordisk”) that Novo Nordisk had elected to terminate the Research Collaboration and Exclusive License Agreement, dated December 14, 2017 (the “Collaboration Agreement”), between Novo Nordisk and the Company, for strategic and business reasons. As a result of the termination of the Collaboration Agreement, the Company will regain worldwide rights to all ligand traps selected under the Collaboration Agreement, along with all rights to develop Keros molecules in diabetes, obesity, nonalcoholic steatohepatitis and cachexia. The termination of the Collaboration Agreement will be effective on April 26, 2021.

Recent Program Highlights:

- **KER-050 for the treatment of ineffective hematopoiesis to address cytopenias:**
 - On October 20, 2020, Keros announced the dosing of the first two participants in its open-label, Phase 2 clinical trial evaluating KER-050 for the treatment of anemia and thrombocytopenia in very low-, low- or intermediate-risk MDS. Keros expects to report initial data from Part 1 of this trial in mid-2021, subject to any delays related to the COVID-19 pandemic.
 - Keros will present two preclinical abstracts on a mouse version of KER-050 highlighting the differentiated mechanism of action and potential of KER-050 to address multiple types of cytopenias at the 62nd American Society of Hematology (“ASH”) Annual Meeting and Exposition, to be held virtually December 5-8, 2020.
- **KER-047 for the treatment of anemia arising from iron imbalance and for the treatment of fibrodysplasia ossificans progressiva (“FOP”):**
 - In August 2020, Keros announced the completion of its planned single and multiple ascending dose cohorts in a Phase 1 clinical trial of KER-047 in healthy volunteers, as well as the expansion of this trial to evaluate additional cohorts of healthy volunteers.
 - In this expanded Phase 1 clinical trial, Keros observed rapid and dose-related increases in serum iron and transferrin saturation in the volunteers who received KER-047. Keros also observed a reduction in hepcidin at each dose level tested in Part 2 of this expanded trial.
 - Keros terminated the trial after determining that the data from the additional cohort, in addition to the data from the planned cohorts, was sufficient to

- inform the design of the expected Phase 2 clinical trials of KER-047, and expects to report topline data at a scientific conference by the end of 2020.
- Keros also expects to commence separate Phase 2 clinical trials in patients with iron deficiency anemia ("IDA") and patients with iron-refractory iron deficiency anemia in 2021. Following the completion of the expected Phase 2 clinical trial of KER-047 in patients with IDA, Keros plans to commence a Phase 2 clinical trial in patients with FOP.
- Keros will present final data from the KER-047 Phase 1 clinical trial at the 62nd ASH Annual Meeting, along with a preclinical abstract highlighting the observed effects of activin receptor-like kinase-2 inhibition on hepcidin levels and iron metabolism.

Third Quarter 2020 Financial Results

Keros reported a net loss of \$12.0 million in the third quarter of 2020 as compared to a net loss of \$3.5 million in the third quarter of 2019. The increase in net loss for the second quarter was largely due to increased research and development efforts as well as the infrastructure needed as a publicly traded company.

Research and development expenses were \$8.4 million for the third quarter of 2020 as compared to \$3.9 million for the same period in 2019. The increase of \$4.5 million was primarily due to additional toxicology studies and manufacturing activities, as well as an increase related to personnel expenses, including additional share-based compensation cost, driven by increased headcount to support the advancement of Keros' pipeline.

General and administrative expenses were \$3.6 million for the third quarter of 2020 as compared to \$1.0 million for the same period in 2019. The increase of \$2.6 million was primarily due to an increase in personnel expenses to support Keros' organizational growth and achievement of Keros' corporate goals, additional share-based compensation costs and an increase in professional fees to support Keros' transition to a public company.

Keros' cash and cash equivalents as of September 30, 2020 was \$133.8 million compared to \$144.7 million as of June 30, 2020. Keros expects that the cash and cash equivalents it had on hand at September 30, 2020 will fund its operating expenses and capital expenditure requirements into the second half of 2022.

About Keros Therapeutics, Inc.

Keros is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel treatments for patients suffering from hematologic and musculoskeletal disorders with high unmet medical need. Keros is a leader in understanding the role of the transforming growth factor-Beta, or TGF- β , family of proteins, which are master regulators of red blood cell and platelet production as well as of the growth, repair and maintenance of muscle and bone. Keros' lead protein therapeutic product candidate, KER-050, is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with myelodysplastic syndromes and in patients with myelofibrosis. Keros' lead small molecule product candidate, KER-047, is being developed for the treatment of anemia resulting from iron imbalance, as well as for the treatment of fibrodysplasia ossificans progressiva. Keros' third product candidate, KER-012, is being developed for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of pulmonary arterial hypertension.

Cautionary Note Regarding Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Words such as "anticipates," "believes," "expects," "intends," "plans," "potential," "projects," "would" and "future" or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: Keros' expectations regarding its growth, strategy, progress and timing of its preclinical studies and clinical trials for KER-047, including its regulatory plans; the potential impact of COVID-19 on Keros' ongoing and planned preclinical studies, clinical trials, business and operations; Keros' plans to present preclinical and clinical data at an upcoming conference; and Keros' expected cash runway. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: Keros' limited operating history and historical losses; Keros' ability to raise additional funding to complete the development and any commercialization of its product candidates; Keros' dependence on the success of its lead product candidates, KER-050 and KER-047; that Keros may be delayed in initiating, enrolling or completing any clinical trials; competition from third parties that are developing products for similar uses; Keros' ability to obtain, maintain and protect its intellectual property; Keros' dependence on third parties in connection with manufacturing, clinical trials and preclinical studies; and risks relating to the impact on Keros' business of the COVID-19 pandemic or similar public health crises.

These and other risks are described more fully in Keros' filings with the Securities and Exchange Commission ("SEC"), including the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 13, 2020, and its other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Keros undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Investor Contact:

Julia Balanova
jbalanova@soleburytrout.com
646-378-2936

KEROS THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019	2020	2019
REVENUE:				
Research collaboration revenue	\$ —	\$ 2,500	\$ —	\$ 7,500
Total revenue	<u>—</u>	<u>2,500</u>	<u>—</u>	<u>7,500</u>
OPERATING EXPENSES:				
Research and development	(8,395)	(3,854)	(24,186)	(13,218)
General and administrative	(3,553)	(972)	(9,180)	(2,117)
Total operating expenses	<u>(11,948)</u>	<u>(4,826)</u>	<u>(33,366)</u>	<u>(15,335)</u>
LOSS FROM OPERATIONS	<u>(11,948)</u>	<u>(2,326)</u>	<u>(33,366)</u>	<u>(7,835)</u>
OTHER INCOME (EXPENSE), NET				
Interest expense, net	(2)	(3)	(5)	(7)
Research and development incentive income	—	—	—	558
Change in fair value of preferred stock tranche obligation	—	(1,235)	(1,490)	(2,486)
Other income (expense), net	(86)	15	4	185
Total other income (expense), net	<u>(88)</u>	<u>(1,223)</u>	<u>(1,491)</u>	<u>(1,750)</u>
Loss before income taxes	<u>(12,036)</u>	<u>(3,549)</u>	<u>(34,857)</u>	<u>(9,585)</u>
Income tax benefit	—	—	172	—
Net loss	<u>\$ (12,036)</u>	<u>\$ (3,549)</u>	<u>\$ (34,685)</u>	<u>\$ (9,585)</u>
Net loss attributable to common stockholders—basic and diluted (Note 10)	<u>\$ (12,036)</u>	<u>\$ (3,999)</u>	<u>\$ (35,697)</u>	<u>\$ (10,935)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.60)</u>	<u>\$ (1.71)</u>	<u>\$ (2.65)</u>	<u>\$ (4.76)</u>
Weighted-average common stock outstanding—basic and diluted	<u>20,175,883</u>	<u>2,342,782</u>	<u>13,452,606</u>	<u>2,296,701</u>

KEROS THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	SEPTEMBER 30, 2020	DECEMBER 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 133,810	\$ 7,020
Prepaid expenses and other current assets	2,606	381
Deferred IPO costs	—	604
Research and development incentive receivable	—	922
Total current assets	136,416	8,927
Operating lease right-of-use assets	976	1,205
Property and equipment, net	739	708
Restricted cash	115	115
TOTAL ASSETS	138,246	10,955
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	1,716	2,088
Current portion of operating lease liabilities	412	376
Accrued expenses and other current liabilities	4,697	2,022
Total current liabilities	6,825	4,486
Operating lease liabilities, net of current portion	586	899
Preferred stock tranche liability	—	4,956
Other liabilities	77	119
Total liabilities	7,488	10,460
Series A convertible preferred stock, par value of \$0.0001 per share; 0 and 10,000,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 0 and 4,607,652 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; liquidation and redemption value of \$0 as of September 30, 2020	—	9,891
Series A-1 convertible preferred stock, par value of \$0.0001 per share; 0 and 800,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 0 and 368,612 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; liquidation and redemption value of \$0 as of September 30, 2020	—	944
Series B-1 convertible preferred stock, par value of \$0.0001 per share; 0 and 3,427,004 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 0 and 1,579,043 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; liquidation and redemption value of \$0 as of September 30, 2020	—	9,106
STOCKHOLDERS' EQUITY (DEFICIT):		
Common stock, par value of \$0.0001 per share; 200,000,000 and 27,000,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 20,185,730 and 2,429,705 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	2	1
Additional paid-in capital	185,091	203
Accumulated deficit	(54,335)	(19,650)
Total stockholders' equity (deficit)	130,758	(19,446)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	138,246	10,955



KEROS
THERAPEUTICS

Corporate Presentation

November 2020

Disclaimer

Statements contained in this presentation regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Words such as “anticipates,” “believes,” “expects,” “intends,” “plans,” “potential,” “may,” “would” and “future” or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: Keros’ expectations regarding its growth, strategy, progress and timing of its preclinical studies and clinical trials for KER-050, KER-047 and KER-012, including its regulatory plans; the potential impact of COVID-19 on Keros’ ongoing and planned preclinical studies, clinical trials, manufacturing and operations; and the potential of Keros’ proprietary discovery approach. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: Keros’ limited operating history and historical losses; Keros’ ability to raise additional funding to complete the development and any commercialization of product candidates; Keros’ dependence on the success of its lead product candidates, KER-050 and KER-047; that Keros may be delayed in initiating enrolling or completing any clinical trials; competition from third parties that are developing products for similar uses; Keros’ ability to obtain, maintain and protect its intellectual property; Keros’ dependence on third parties in connection with manufacturing, clinical trials and pre-clinical studies; and relating to the impact on our business of the COVID-19 pandemic or similar public health crises.

These and other risks are described more fully in Keros’ filings with the Securities and Exchange Commission (“SEC”), including the “Risk Factors” section of the Company’s Quarterly Report on Form 10-Q, filed with the SEC on November 10, 2020, and its other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. Except to the extent required by law, Keros undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company’s own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.



Harnessing the Powerful Biology of the TGF- β Superfamily

- Clinical-stage biopharmaceutical company developing novel therapeutics that target the TGF- β superfamily
- Approach validated by marketed products, Infuse (BMP2) for spinal fusion and Reblozyl® (modified activin receptor IIB) for treatment of anemia in β -thalassemia and myelodysplastic syndromes
- Leveraging our extensive experience in TGF- β superfamily protein structure, function and protein engineering to generate a clinical pipeline of differentiated therapeutics:

KER-050: Modified activin receptor IIA (ActRIIA) ligand trap

- Designed to address ineffective hematopoiesis by modulating TGF- β superfamily signaling
- Potential to correct multiple cytopenias in patients with MDS and myelofibrosis (MF)

KER-047: Activin receptor-like kinase-2 (ALK2) inhibitor being developed for the treatment of anemia resulting from iron imbalance, including iron deficiency anemia (IDA) and iron-refractory iron deficiency anemia (IRIDA), as well as fibrodysplasia ossificans progressiva (FOP)

- Expect to initiate two Phase 2 trials in 2021 – one in patients with IDA and one in patients with IRIDA
- Potential to treat anemia associated with chronic inflammation

KER-012: Proprietary selective activin receptor ligand trap in preclinical development for the treatment of disorders associated with bone loss and pulmonary arterial hypertension (PAH)



Keros is Developing Differentiated Clinical Assets in Hematologic and Musculoskeletal Disorders

Program	Asset	Phase of Development				Status	Next Milestones*
		Preclinical	Phase 1	Phase 2	Phase 3		
Hematology	KER-050 (therapeutic protein)	Myelodysplastic syndromes (MDS)				Initiated Phase 2 clinical trial	Initial data: mid-2021
		Myelofibrosis (MF)				Completed Phase 1 clinical trial	Initiate Phase 2 clinical trial: 2021
Musculoskeletal	KER-047 (small molecule)	Iron deficiency anemia				Completed expanded Phase 1 clinical trial	Present topline data: end of 2020
		Anemia from high hepcidin					
Preclinical Pipeline	KER-012 (therapeutic protein)	Fibrodysplasia Ossificans Progressiva (FOP)				Ongoing preclinical studies	Initiate Phase 1 clinical trial: H2 2021
		Pulmonary arterial hypertension		Bone disorders			

* Anticipated clinical milestones are subject to the impact of COVID-19 on our business.





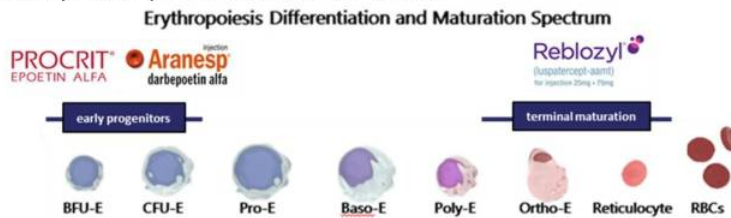
KER-050

A novel treatment designed to address diseases arising from ineffective hematopoiesis

- Myelodysplastic syndromes
 - Myelofibrosis
-

Myelodysplastic Syndromes (MDS) Overview

- Hematologic malignancy predominantly affecting the elderly, resulting in multiple cytopenias (anemia, thrombocytopenia, neutropenia) due to ineffective hematopoiesis
 - 60,000-170,000 MDS patients in U.S.*
 - 15,000-20,000 newly diagnosed MDS patients in U.S. each year*
- Platelet transfusion for thrombocytopenia
- 90% of patients are anemic and 40-65% have thrombocytopenia
- Anemia treatments include red blood cell (RBC) transfusions, erythropoiesis-stimulating agents (ESAs) and Reblozyl
 - ESAs only impact early progenitors in red blood cell lineage and benefit is limited to patients with low transfusion burden endogenous EPO levels
 - Reblozyl® approved for treatment of anemia in RS positive patients
 - Approximately 15% of all MDS patients are RS positive and have defects in terminal maturation
 - 38% responders vs 13% placebo
 - Similar to ESAs, benefit primarily in low transfusion burden



*MDS Foundation

KER-050 is a Modified ActRII Fusion Protein

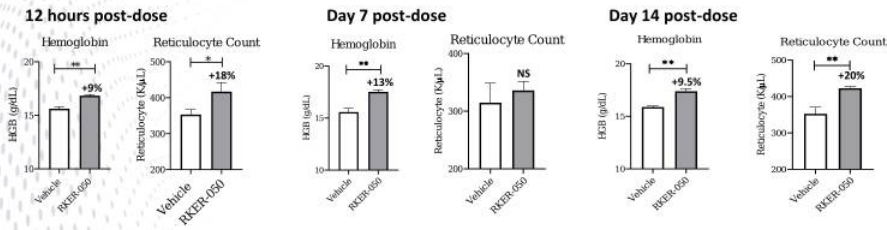
- Activin receptors are expressed on hematopoietic cells and modulate differentiation of precursor cells
- KER-050 is a ligand trap composed of a modified extracellular domain of activin receptor II_B (ActRIIA) fused to the Fc region of human IgG
- KER-050 is designed to increase RBC and platelet production by inhibiting the signaling of ligands through activin receptors
- Preclinical data demonstrate that increased RBCs by potentially increasing differentiation through multiple stages of erythropoiesis
 - Observed increases in platelets also potentially supports action throughout the thrombopoiesis pathway
- Phase 1 clinical trial of KER-050 recapitulated preclinical data with observed rapid, sustained and dose-dependent increases in RBCs and platelets



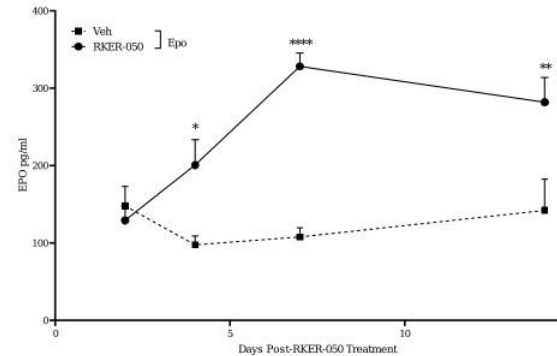
Treatment with RKER-50 Increased Erythropoiesis by Potentially Promoting Maturation at Multiple Stages and Increased Serum Erythropoietin

- In a preclinical study conducted in mice, a single, subcutaneous 10 mg/kg dose of a mouse version of KER-050 (RKER-050) resulted in:
 - Rapid increase in RBCs
 - Sustained increase continuing to at least 14 days post-dose
 - 2-3-fold increase in circulating erythropoietin
- KER-050 potentially acts on multiple stages across the RBC differentiation spectrum, including common myeloid cells

Increase in Red Blood Cells and Reticulocytes in Mice



Observed Increase in Serum Erythropoietin in Mice



* P value ≤ 0.05 ; ** P value ≤ 0.01 ; **** P value ≤ 0.0001



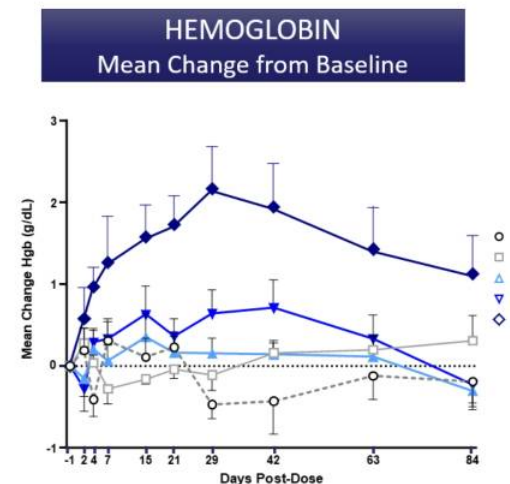
KER-050 Completed First-in-human Trial

- First-in-human trial was designed to explore the safety, tolerability and PK in healthy volunteers with a secondary objective to evaluate changes in PD (hematology and bone biomarkers)
- Observed that KER-050 drug levels were dose proportional in Part 1 of the KER-050 Phase 1 clinical trial, with a mean half-life of approximately 12 days
 - The half-life coupled with the pharmacodynamic effect observed in the hematologic parameters support the potential for administration of monthly or less frequent dosing
- Observed to be well tolerated at dose levels up to 4.5 mg/kg, the highest dose level tested
- Notable adverse event:
 - Reversible, mild hypertension events observed only in subjects with an approximately 3 g/dL increase in hemoglobin



KER-050 Phase 1 Clinical Trial Recapitulated Learnings from Preclinical Studies

- Single, subcutaneous administration of KER-050 in healthy volunteers
- Observed rapid increase in red blood cell parameters is supportive of acceleration of maturation of late-stage precursors
 - Reticulocytes, red blood cells and hemoglobin
- Observed sustained increase from single dose supports monthly or less frequent dosing
 - Increases in RBC observed through day 29 are supportive of KER-050 acting on multiple stages of erythropoiesis
 - Maximum drug levels were observed on day 4

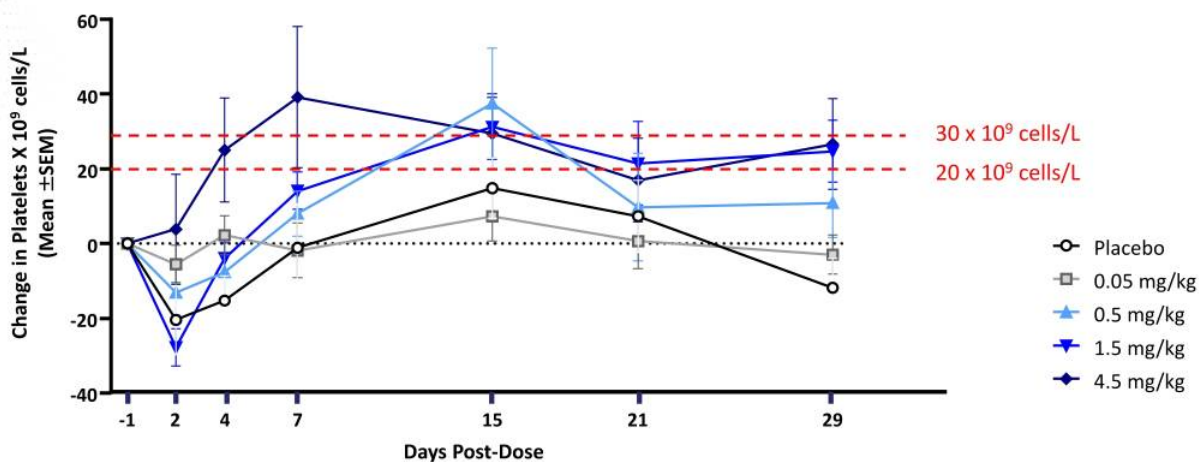


Mean change of >1.5 g/dl
observed by day 15
in 4.5 mg/kg cohort



KER-050 Treatment was Observed to Lead to Clinically Meaningful Changes in Platelets after a Single Dose

Mean Change from Baseline in Platelets at Each Dose



KER-050 has a Potentially Differentiated Mechanism of Action

- Robust and sustained increases observed in RBCs, hemoglobin and reticulocytes support the potential administration of monthly or less frequent dosing
- Observed sustained response potentially supports the dual mechanism of promoting early and late stages of erythropoiesis

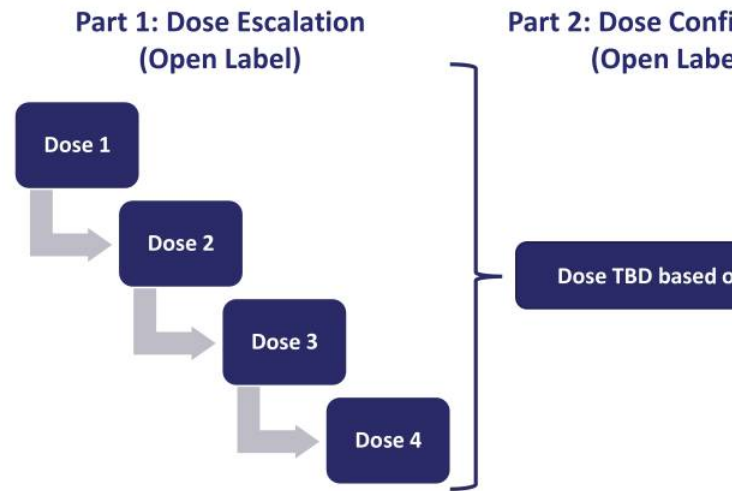


- Clinically meaningful increase observed in platelets after a single dose, which we believe differentiates 050 from other agents that only affect RBCs



Initiated a Phase 2 Trial of KER-050 in MDS

- Open label Phase 2 trial in two parts to explore changes in hematology with treatment in patients with MDS
 - Red blood cell parameters
 - Platelets
- 12-week treatment with monthly dosing and 12-week follow up
- Part 1: Dose escalation to evaluate response in RS positive and non-RS patients
- Part 2: Dose confirmation



Treatment in Parts 1 and 2: 12 weeks
Safety follow up: 12 weeks



Myelofibrosis (MF) is Characterized by Ineffective Hematopoiesis

- Molecular abnormalities in JAK-STAT pathway result in expansion of RBC and platelet precursors and subsequent ineffective hematopoiesis
- Megakaryocyte accumulation/breakdown is implicated in the inducement of bone marrow fibrosis
- KER-050 increased RBCs and platelets in our Phase 1 clinical trial
- Plan to initiate a Phase 2 trial in MF in 2021, evaluating effect on platelets and RBCs
 - We believe that KER-050 has the potential to address ineffective hematopoiesis, which is central to MF

16,000-18,500

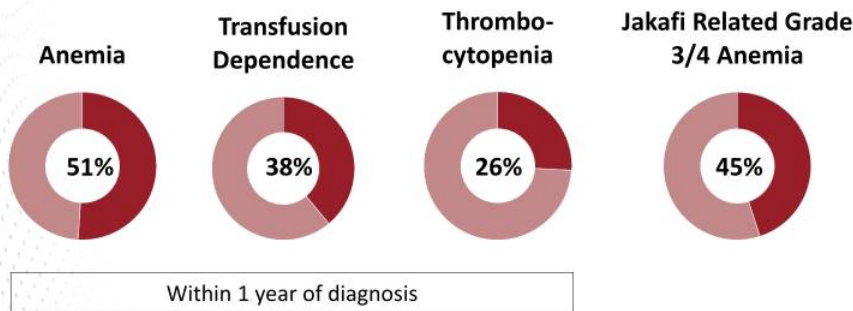
Prevalence of MF patients in US*

>3,000

New MF patients diagnosed each year**

~100 %

Nearly all MF patients become transfusion-dependent***



*Gangat 2011; **Srouf 2016; ***Naymağ



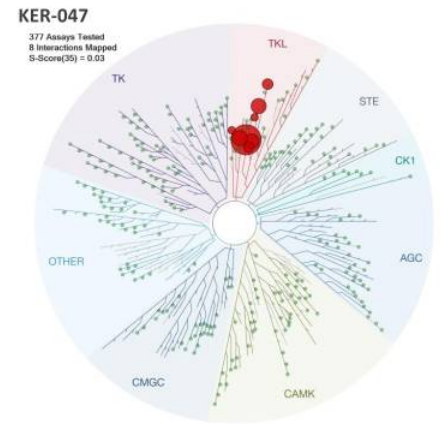
KER-047

A novel treatment designed to address:

- Anemia resulting from iron imbalance
 - Iron deficiency anemia
 - IRIDA
 - Fibrodysplasia ossificans progressiva (FOP)
-

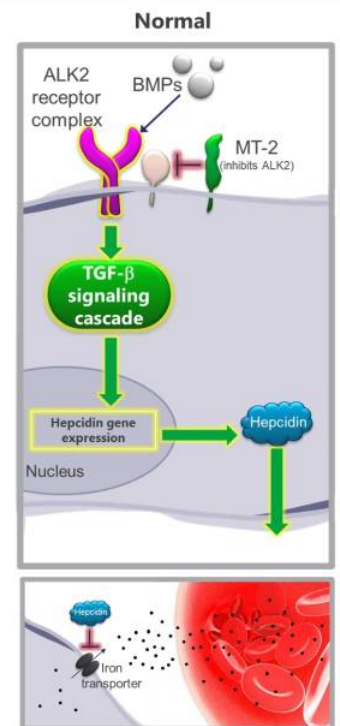
KER-047: A Potentially Potent and Selective ALK2 Inhibitor

- **Small molecule inhibitor of the activin receptor-like kinase-2 (ALK2) kinase domain**
- **Potency:** Low nanomolar IC_{50}
- **Selectivity:** Highly selective over kinases outside of the TGF- β superfamily as well as other, structurally similar TGF- β receptors
 - Data from cell-based reporter assays established > 20-fold potency for ALK2 compared to ALK1 and ALK5, which have 77% and 65% homology to ALK2, respectively (Kingsley, D.M., 1994)
- **PK/ADME:** Suitable for 1x daily oral dosing



ALK2 Regulates Hepcidin and Iron Homeostasis

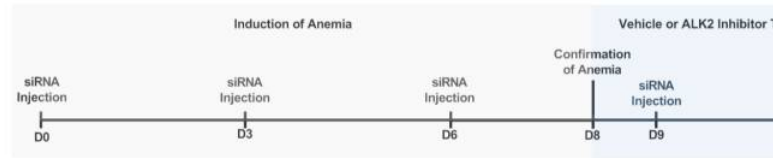
- ALK2 signaling in the liver controls hepcidin expression, a hormone that controls iron homeostasis
- Excessive ALK2 signaling results in high hepcidin and a shortage of iron availability for RBC production
- ALK2 signaling requires BMP ligand and the co-receptor hemojuvelin
- Hepcidin expression is tightly regulated and controls expression of the ALK2 suppressor protease MT-2
 - The genetic disease iron-refractory iron deficiency anemia (IRIDA) is characterized by loss of MT-2
- High hepcidin has also been implicated in anemia of chronic disease
- Modulating ALK2 signaling will normalize high hepcidin levels, restore serum iron and ameliorate anemia



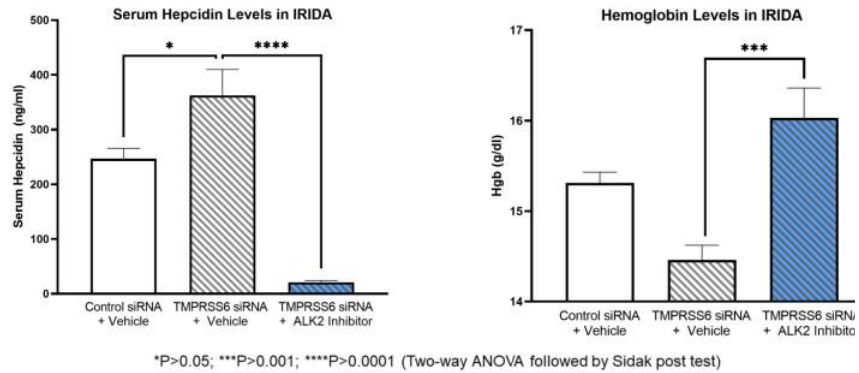
Keros ALK2 Inhibitors Shown to Resolve Anemia in the Mouse Model of IRIDA

- TMPRSS6 encodes MT-2, the protease that suppresses ALK2 signaling
- MT-2/TMPRSS6 deficiency results in IRIDA
- siRNA knockdown of TMPRSS6 in mice mimics changes seen in human IRIDA patients
 - Increases hepcidin and reduces hemoglobin
- Our small molecule ALK2 inhibitor reversed high hepcidin and ameliorated anemia resulting from TMPRSS6 deficiency in wild-type mice

Mouse IRIDA Model Protocol Timeline



Mouse IRIDA Model Data



KER-047: Expanded Phase 1 Clinical Trial Recapitulated the Observations from Preclinical Studies

- All single ascending and multiple ascending dose cohorts evaluated (including additional cohort) (“expanded trial”)
- The objective of the Phase 1 clinical trial was to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic effects of single and multiple ascending dose levels of KER-047 in healthy volunteers
 - In the multiple ascending dose cohorts, KER-047 was administered as daily doses of 50-350 mg for approximately 7 days
- Multiple pharmacodynamic biomarkers were included to assess KER-047’s inhibition of ALK2
 - Reduction in hepcidin was observed at each dose level tested in Part 2 of the expanded trial
 - Observed rapid and dose-related increases in serum iron and transferrin saturation in the expanded trial
 - We believe iron mobilization led to increased iron bioavailability for incorporation into reticulocyte hemoglobin. These erythroid precursors potentially would continue maturation into hemoglobin-rich red blood cells
- We also observed decreases in lymphocytes following peak increases in serum iron in the expanded trial
- Reductions in total cholesterol, low-density lipoproteins (LDL) and high-density lipoproteins were observed in Part 2 of the expanded trial. The reductions in total cholesterol and LDL were achieved rapidly with a mean reduction of more than 20% at the highest dose, following seven days of dosing.
- There were no serious adverse events reported in either part of this expanded trial
- Most common adverse events observed: abdominal discomfort, chills, decreased appetite, diarrhea, dizziness, fatigue, gastroenteritis, headache, lymphopenia, myalgia, nausea, neutropenia, pyrexia, rhinorrhea, tonsillitis, upper abdominal pain and vomiting



Phase 2 Trials to Provide Proof-of-Concept for Treatment of Anemia Resulting from Iron Imbalance, Including IDA and IRIDA

Iron Deficiency Anemia

- KER-047 is designed to re-establish normal iron homeostasis by mobilizing iron out of tissues, thereby ameliorating anemia
- We expect to initiate a Phase 2 clinical trial in patients with iron deficiency anemia in 2021

IRIDA

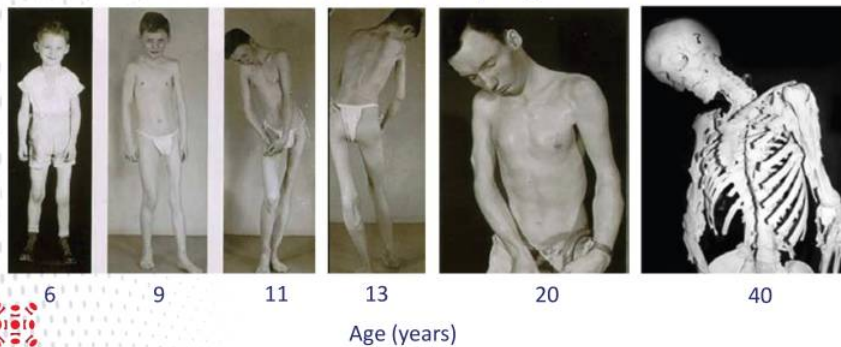
- KER-047 is designed to normalize high hepatic iron levels, restore serum iron and ameliorate anemia
- We expect to initiate a Phase 2 clinical trial in patients with IRIDA in 2021



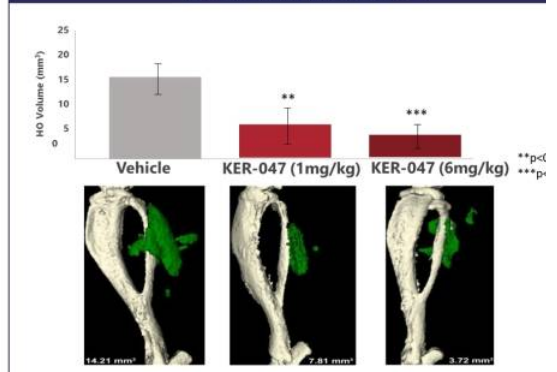
ALK2 Mutation is a Driver of FOP

- FOP is a rare genetic disease in which muscles and connective tissues transform into bone
- No cure or effective treatments
 - Most patients are confined to a wheelchair by third decade of life
 - Typical life expectancy – 40 years
- Caused by single amino acid mutations in ALK2 that lead to gain-of-function
- KER-047 is designed to target ALK2
 - Preclinical studies conducted in young animals demonstrated that ALK2 inhibition did not result in growth plate ablation or synovial joint malformations

An example of FOP progression



KER-047 dose-dependently reduced heterotopic ossification genetic mouse model of FOP





KER-012

A preclinical program designed to address

- Bone loss disorders such as osteoporosis and osteogenesis imperfecta
 - Pulmonary arterial hypertension (PAH)
-

KER-012: Preclinical Product Candidate

- Proprietary selective activin receptor ligand trap in preclinical development for the treatment of pulmonary arterial hypertension (PAH) and bone disorders
- In preclinical studies, KER-012:
 - Demonstrated high affinity for, and potent inhibition of, ligands involved in the regulation of bone homeostasis
 - Increased bone mineral density and trabecular bone volume in wild-type mice and mice with established osteoporosis
 - Did not increase red blood cell production in cynomolgus monkeys
- In a rat model of PAH, rats receiving a rodent version of KER-012 (RKER-012) were protected from the thickening of the right ventricular wall
 - In addition, rats receiving RKER-012 were protected from PAH-associated bone loss
- We believe KER-012 has the potential to increase the signaling of BMP pathways by inhibiting activin A and activin B signaling and, consequently, treat diseases such as PAH that are associated with reduced BMP signaling





Keros Summary



We Believe Keros is Positioned for Clinical and Commercial Success

- Keros is focused on the development of novel TGF- β therapeutics
 - Robust biology that has been validated in the clinic
- Keros is well-positioned to harness the potential of the TGF- β superfamily
 - ActRII program (KER-050) is in a Phase 2 trial in patients with MDS and we expect to initiate a Phase 2 trial in patients with MF in 2021
 - Multiple Phase 2 trials for ALK2 program (KER-047) expected to commence in 2021
 - KER-012 is a selective activin receptor ligand trap expected to enter a Phase 1 trial in H2 2021
 - Clinical programs have potentially differentiated mechanism of action
- Our discovery approach has the potential to identify additional molecules with differentiated profiles from existing third-party products and product candidates
 - Pipeline of preclinical assets: bone, muscle and pulmonary



Anticipated Key Milestones*

KER-050

- Present additional preclinical data on mechanism Q4 2020 (ASH 2020)
- Announce initial data for Phase 2 trial in MDS Mid-2021
- Initiate Phase 2 trial in myelofibrosis 2021

KER-047

- Present Phase 1 healthy volunteer data Q4 2020 (ASH 2020)
- Initiate Phase 2 trial in IDA 2021
- Initiate Phase 2 trial in IRIDA 2021

KER-012

- Present preclinical data on PAH at major conference 2021
- Initiate Phase 1 trial in healthy volunteers H2 2021

*Anticipated preclinical and clinical milestones are subject to the impact of COVID-19 on our business.





Thank You
