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 14, 2022

Neoleukin Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36327**	**98-0542593**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

188 East Blaine Street, Suite 450
Seattle, Washington 98102
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (866) 245-0312

N/A
(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 Instruction 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, $0.000001 par value	**NLTX**	**The Nasdaq Global 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.

o

Item 2.02 Results of Operations and Financial Condition

On November 14, 2022, Neoleukin Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the quarter ended September 30, 2022. The full text of the press release announcing such results is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure

The Company has prepared investor presentation materials with information about the Company, which it intends to use as part of investor presentations. A copy of the investor presentation materials to be used by management for presentations is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this current report on Form 8-K and in Exhibits 99.1 and 99.2 attached hereto is being furnished, but shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and is not incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Number	Description
99.1	Press Release of Neoleukin Therapeutics, Inc. dated November 14, 2022
99.2	Presentation of Neoleukin Therapeutics, Inc. dated November 2022
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURE

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

Date: November 14, 2022

Neoleukin Therapeutics, Inc.
By: /s/ Jonathan G. Drachman
Name: Jonathan G. Drachman
Title: President and Chief Executive Officer

Neoleukin Therapeutics Announces Third Quarter 2022 Financial Results and Corporate Update

– Development of NL-201 to be discontinued for strategic reasons –
– Company to focus on next-generation de novo *proteins and core technology –*
– Company restructuring to extend cash runway into the second half of 2025 –

SEATTLE, Washington, November 14, 2022 – Neoleukin Therapeutics, Inc., “Neoleukin” (NASDAQ:NLTX), a biopharmaceutical company utilizing sophisticated computational methods to design *de novo* protein therapeutics, today announced financial results for the third quarter ended September 30, 2022 as well as a strategic decision to discontinue development of NL-201, a fully *de novo* IL-2/IL-15 agonist, and focus on advancing next-generation *de novo* protein therapeutics based on Neoleukin's expertise in designing and testing novel cytokine mimetics and experience with advanced machine learning.

"We will be using the information we have learned from the development of NL-201 and advances in protein design to build the next generation of *de novo* protein therapeutics," said Jonathan Drachman, M.D., Chief Executive Officer at Neoleukin. "We expect to focus on technology that widens the therapeutic window, such as the development of targeted and conditionally activated molecules to create potent immune agonists. We believe we are well positioned to do this work based on our expertise in *de novo* protein design combined with our experience in advanced machine learning and neural networks, which allows us to predict and create structures for *de novo* proteins with more sophisticated and dynamic structural elements than was previously possible."

"This coincides with a strategic decision to discontinue development of NL-201, which we believe was the first fully *de novo* protein to be evaluated in clinical trials," said Dr. Drachman. "We are grateful to the patients and families that participated in this Phase 1 trial and to the investigators and study personnel who enabled rapid testing of NL-201 during a global pandemic."

Discontinuation of NL-201 Development

Neoleukin announced today that it is discontinuing development of NL-201, its first de novo cytokine mimetic to be tested in patients. Preliminary monotherapy data from the Phase 1 study of NL-201 demonstrated engagement of the target receptor, expected pharmacodynamic changes for a potent IL-2/IL-15 agonist, and did not demonstrate significant immunogenicity even after multiple cycles of therapy—an important de-risking of the potential for *de novo* proteins that may be administered over many weeks and months. However, based on a review of the preliminary data, the expected benefit to risk ratio for patients, and recent developments in the field of IL-2 therapeutics, Neoleukin determined that the resources required to continue development would be better applied to advancing the next generation of *de novo* protein therapeutics.

Corporate Reorganization

As a result of the decision to discontinue development of NL-201, on November 12, 2022, Neoleukin's Board of Directors approved a restructuring plan, including a reduction in force of approximately 40%. Cost savings as a result of this reduction in force as well as the discontinuation of development of NL-201 are expected to extend Neoleukin's existing cash runway into the second half of 2025.

Summary of Financial Results

Cash Position: Cash, cash equivalents, and short-term investments totaled $106.9 million as of September 30, 2022, compared to $142.5 million as of December 31, 2021.

R&D Expenses: Research and development expenses for the third quarter of 2022 decreased to $9.5 million from $9.9 million for the third quarter of 2021. The decrease was primarily due to a decrease in personnel-related costs, partially offset by increases in costs related to the Phase 1 clinical trial of NL-201.

G&A Expenses: General and administrative expenses for the third quarter of 2022 decreased to $4.1 million from $5.6 million for the third quarter of 2021. The decrease was primarily attributable to decreases in personnel-related and facility-related costs.

Net Loss: Net loss for the third quarter of 2022 was $13.1 million compared to a net loss of $15.4 million in the third quarter of 2021.

About Neoleukin Therapeutics, Inc.

Neoleukin is a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation and autoimmunity using *de novo* protein design technology. Neoleukin uses sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins.

Safe Harbor / Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the therapeutic properties and potential of the company's *de novo* protein design technology, cost and timing of discontinuing the clinical trial for NL-201, expectations regarding the planned corporate restructuring and any cost savings therefrom, expectations regarding cash forecasts, and planned clinical and development activities and

timelines. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties, including risks and uncertainties related to the company's cash forecasts, the company's ability to advance its product candidates, the receipt and timing of potential regulatory submissions, designations, approvals and commercialization of product candidates, the company's ability to protect its intellectual property, the timing and results of preclinical and clinical trials, changes to laws or regulations, market conditions, geopolitical events, and further impacts of COVID-19, that could cause actual results to differ materially from what Neoleukin expects. Further information on potential risk factors that could affect Neoleukin's business and its financial results are detailed under the heading "Risk Factors" included in Neoleukin's Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K filed from time to time with the Securities and Exchange Commission (SEC). Neoleukin undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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jrathbun@neoleukin.com

Investors
Solebury Trout
Alexandra Roy
617-221-9197
investors@neoleukin.com

NEOLEUKIN THERAPEUTICS, INC.

Condensed balance sheet data

(In thousands of U.S. dollars)

	September 30, 2022	December 31, 2021
Assets		
Cash, cash equivalents, and short-term investments	$ 106,878	$ 142,467
Other current assets	1,979	1,522
Non-current assets	17,719	19,274
Total assets	$ 126,576	$ 163,263
Liabilities		
Current liabilities	$ 10,237	$ 8,636
Non-current liabilities	10,692	11,763
Total liabilities	20,929	20,399
Stockholders' equity	105,647	142,864
Total liabilities and stockholders' equity	$ 126,576	$ 163,263

NEOLEUKIN THERAPEUTICS, INC.

Condensed statements of operations and comprehensive income (loss)

(In thousands of U.S. dollars, except per share and share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 9,471	$ 9,896	$22 $ 31,128	$ 29,402
General and administrative	4,138	5,556	13,718	16,122
Total operating expenses	13,609	15,452	44,846	45,524
Loss from operations	(13,609)	(15,452)	(44,846)	(45,524)
Interest income	559	6	766	14
Other income (loss), net	(22)	—	(32)	(15)
Net loss	$ (13,072)	$ (15,446)	$ (44,112)	$ (45,525)
Comprehensive income (loss):				
Unrealized loss on available-for-sale securities	(20)	—	(92)	—
Comprehensive loss	$ (13,092)	$ (15,446)	$ (44,204)	$ (45,525)
Net loss per share – basic and diluted	$ (0.24)	$ (0.28)	$ (0.80)	$ (0.83)
Basic and diluted weighted average common shares outstanding	55,251,039	55,087,777	55,199,822	55,020,059

Exhib

Corporate Presentation

November 2022

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Forward Looking Statements

Certain of the statements made in these slides and the accompanying oral presentation are forward looking, including those relating to Neoleukin's business, strategy, future operations, advancement of its product candidates and product pipeline, expectations and timing of the Company's strategic plans for development, the potential for future clinical development of product candidates, including expectations regarding timing of regulatory submissions and initiation of clinical trials, regulator requirements for initiation of clinical trials and registration of product candidates, properties of its product candidates, availability of data, the use and sufficiency of its cash resources, and other statements containing the words "anticipate," "believe," "expect," "may," "plan," "project," "potential," "will," "would," "could," "continue," and similar expressions. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: the ability of the Company to execute on its strate plan, including success in development of new immunotherapies, the ability to bring any development candidates forward fro the research phase into development and approval for clinical trial; its ability to obtain and maintain regulatory approval for a product candidates and the potential safety, efficacy or clinical utility of or any product candidates; cost and timing expectatio for the discontinuation of NL-201; further impacts of COVID-19, supply chain disruptions, or other global economic and geopolitical events on its operations; and other factors discussed in the "Risk Factors" section and elsewhere in the Company' Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and subsequent reports as filed with the Securities and Exchange Commission. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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We use protein design to reinvent how therapies are created with a goal to meaningfully improve patients' lives

Neoleukin is a pioneer in *de novo* protein development, leveraging computational methods to create new therapies. This new approach has unlimited potential to treat human disease by improving on nature, designing for life. We are building a company with a vibrant and inclusive culture that we believe will make a meaningful impact for patients, ou people and our community.

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Neoleukin: Leader in *de novo* Protein Therapeutics

2018

NEOLEUKIN FOUNDED

Computational methods enable fully *de novo* protein design

Scientists and technology spun out of University of Washington

2019

MERGER COMPLETED

NASDAQ listing (NLTX) after merger with Aquinox

More than $140M raised through merger and follow-on offering

2020

FIRST IND SUBMITTED

First IND of fully *de novo* protein (NL-201)

Neoleukin scientists create second fully *de novo* protein (NL-CVX1)

2021

PHASE 1 TRIAL INITIATED

First patients treated with fully *de novo* protein

2022

MACHINE LEARNING

Machine learning/neural network technology enables rapid drug discovery

FUTURE

EXPAND *DE NOVO* PROTEIN PIPELINE

Multiple fully *de novo* molecules expected to e development in oncology and autoimmune disease

Innovative approaches to drug delivery, conditiona activation, and affinity optimization to improve therapeutic index

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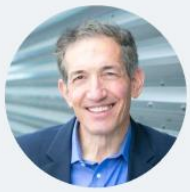
Leadership Team



Jonathan Drachman, M.D.
Chief Executive Officer
PRIOR
CMO, EVP R&D
Seagen

Bill Arthur, Ph.D.
VP & Head of Research
PRIOR
Seagen
Merck & Co.

Priti Patel, M.D., M
Chief Medical Officer
PRIOR
AstraZeneca
Acerta Pharma

Donna Cochener
General Counsel, SVP Legal
PRIOR
HomeStreet
Davis Wright Tremaine

Carl Walkey, Ph.D.
Senior VP, Corporate Development
PRIOR
Postdoctoral Fellow, UW-IPD

Sean Smith
VP, Finance
PRIOR
Aptevo Therapeutics
KPMG

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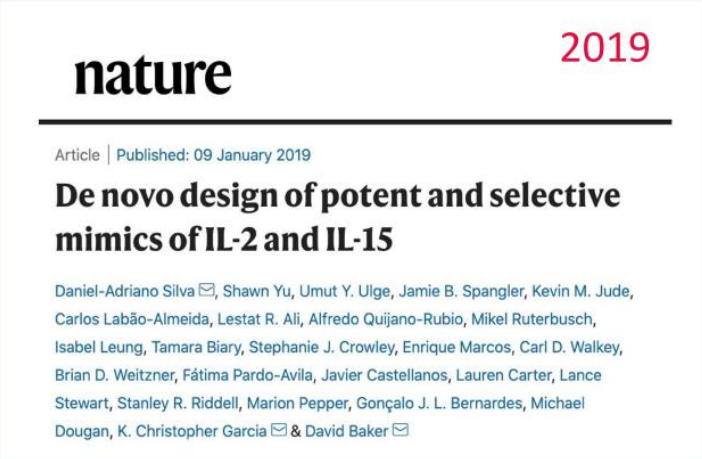
Better Therapies by Design

Functional de novo proteins



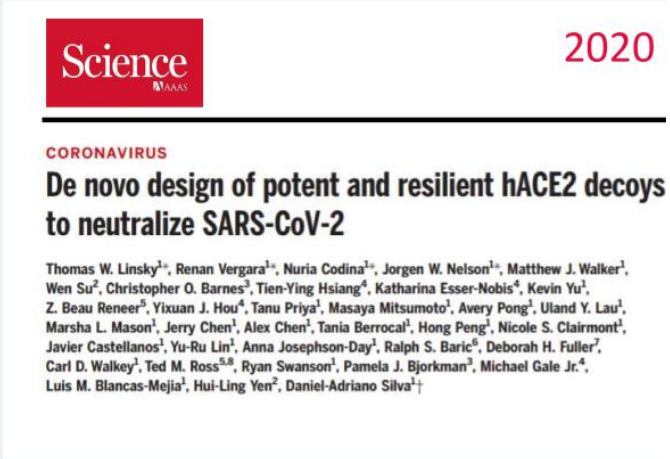
nature

2019

Article | Published: 09 January 2019

De novo design of potent and selective mimics of IL-2 and IL-15

Daniel-Adriano Silva, Shawn Yu, Umut Y. Ulge, Jamie B. Spangler, Kevin M. Jude, Carlos Labão-Almeida, Lestat R. Ali, Alfredo Quijano-Rubio, Mikel Ruterbusch, Isabel Leung, Tamara Biary, Stephanie J. Crowley, Enrique Marcos, Carl D. Walkey, Brian D. Weitzner, Fátima Pardo-Avila, Javier Castellanos, Lauren Carter, Lance Stewart, Stanley R. Riddell, Marion Pepper, Gonçalo J. L. Bernardes, Michael Dougan, K. Christopher Garcia & David Baker



Science

2020

CORONAVIRUS

De novo design of potent and resilient hACE2 decoys to neutralize SARS-CoV-2

Thomas W. Linsky, Renan Vergara, Nuria Codina, Jorgen W. Nelson, Matthew J. Walker, Wen Su, Christopher O. Barnes, Tien-Ying Hsiang, Katharina Esser-Nobis, Kevin Yu, Z. Beau Reneer, Yixuan J. Hou, Tanu Priya, Masaya Mitsumoto, Avery Pong, Uland Y. Lau, Marsha L. Mason, Jerry Chen, Alex Chen, Tania Berrocal, Hong Peng, Nicole S. Clairmont, Javier Castellanos, Yu-Ru Lin, Anna Josephson-Day, Ralph S. Baric, Deborah H. Fuller, Carl D. Walkey, Ted M. Ross, Ryan Swanson, Pamela J. Bjorkman, Michael Gale Jr., Luis M. Blancas-Mejia, Hui-Ling Yen, Daniel-Adriano Silva

- Scientific founders are world leaders in *de novo* protein design
- Technology originated at University of Washington Institute for Protein Design
- Exclusive license obtained for commercialization of NL-201 and other *de novo* protein assets

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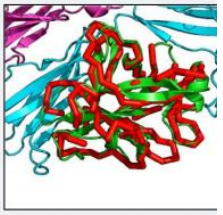
De Novo Protein Design

- Amino acids are nature's building blocks for proteins
- The order they are arranged in determines how a protein folds, what it binds to, and what it does
- Decades of research into protein folding, thermodynamics, and advances in computational power has resulted in the ability to design proteins that have never existed before



Neoleukin is leading the revolution in *de novo* protein therapeutics

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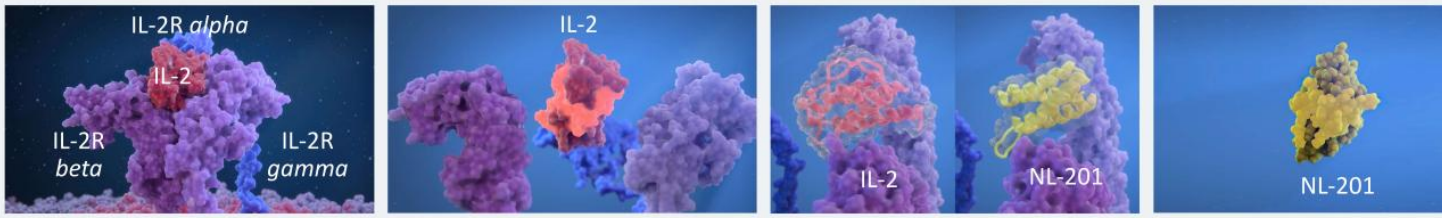
Neoleukin™ *de novo* design methodology



1. Develop an accurate structural model of target
2. Identify regions of intermolecular contact
3. Design an idealized topology
4. Assign optimal amin acid sequences

- High-resolution structural models of native ligand-receptor interactions guide design
- Iterative process from multiple scientific disciplines to refine designs
- Early methods focused on less complex structures

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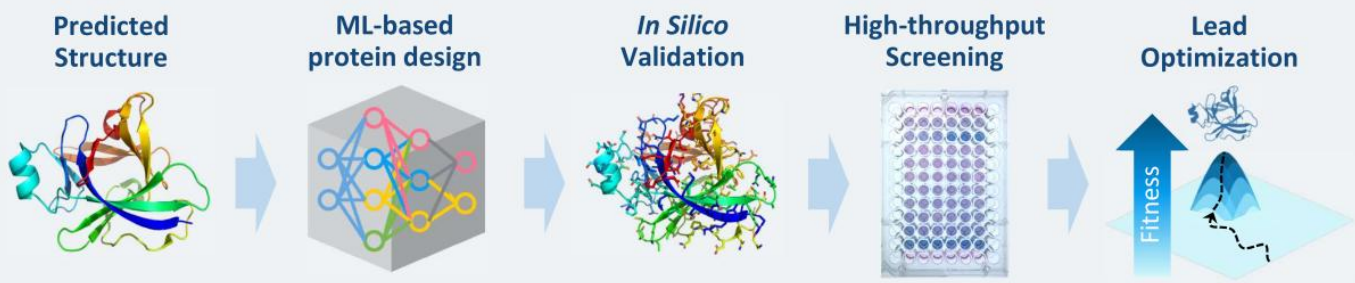
Evolution of Neoleukin™ *De Novo* Protein Technology

Accelerating speed and accuracy



- New methodology combines machine-learning (ML) based sequence design and structure prediction with high-throug screening.
- ML-based methods enable more efficient protein design with higher success rates and using a fraction of the computi power.
- We can now develop from a more expanded landscape of protein topologies that were not accessible by traditional methods.

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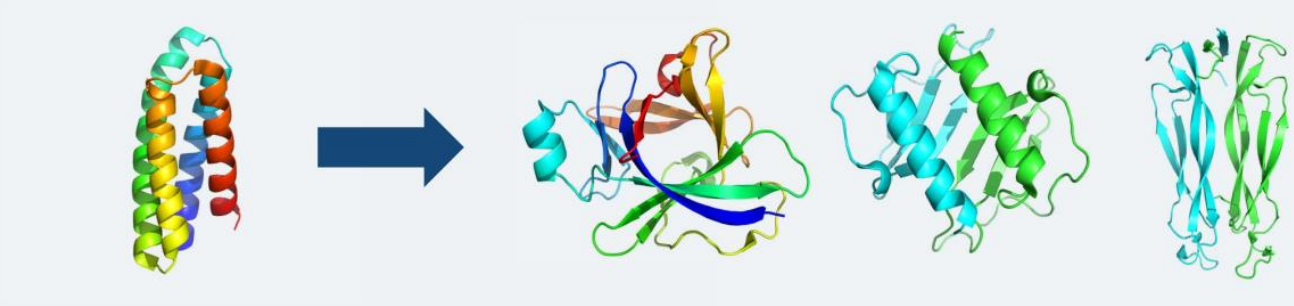
Adding Machine Learning to Protein Design

Building the next generation of de novo proteins

New methods are required to tackle more complex topologies



4-helix bundle

Some cytokine families have complex structures

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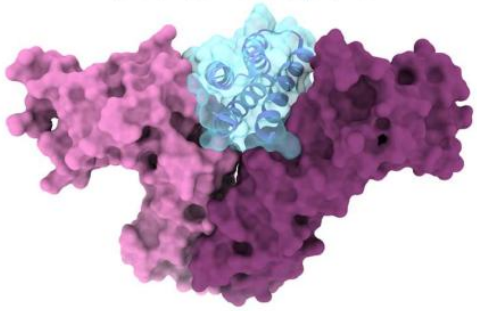
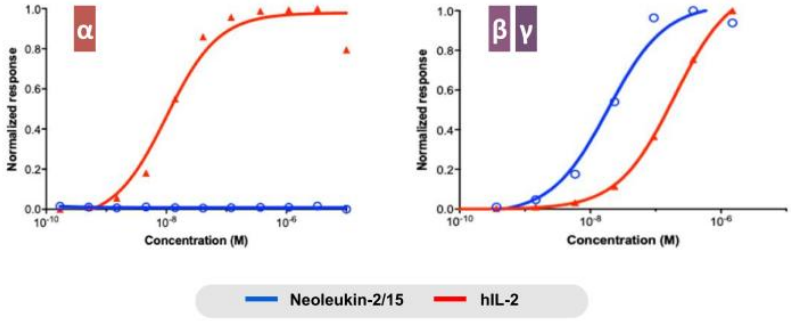
NL-201: *de novo* non-alpha IL-2/IL-15 agonist

Potent, stable, no bias toward Tregs or endothelial cells

14% Conserved sequence



Source: Silva et al. *Nature*, 565, 186-191 (2019)



NL-201 is a de novo protein designed with no alpha subunit interaction and increased beta/gamma binding

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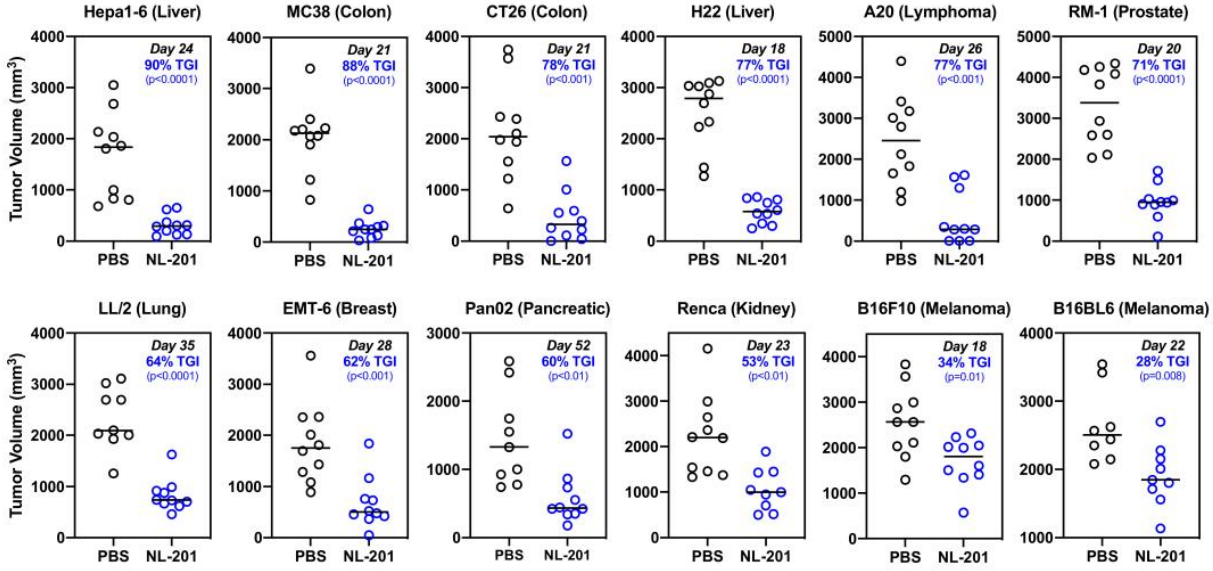
NL-201 Demonstrates Robust Single-Agent Activity in Multiple Tumor Models



- NL-201 was administered QW when tumors rea ~100mm3
- Tumor growth inhibition (TGI) is reported in each vs. control.
- NL-201 significan inhibited tumor growth in all mo including those t are refractory to checkpoint inhib

Walkey et. al, AACR Virtual Annual Meeting II, Abstract #4518, June 2020

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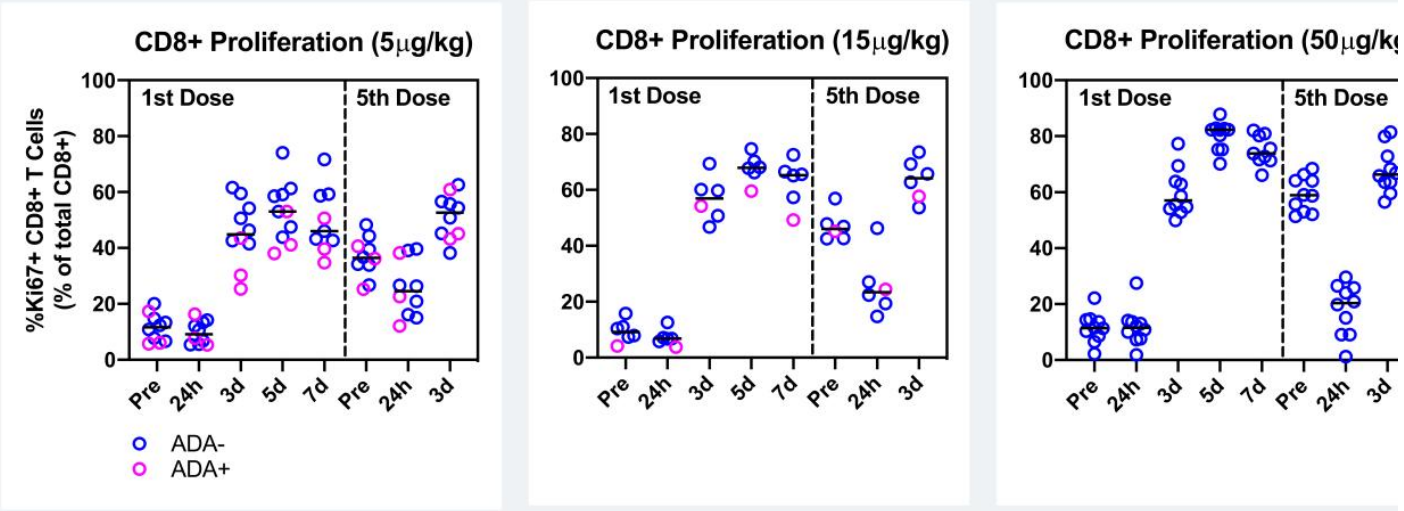
Similar Pharmacodynamic Response in ADA+ vs ADA- NH



Walkey et. al, AACR Virtual Annual Meeting II, Abstract #4518, June 2020

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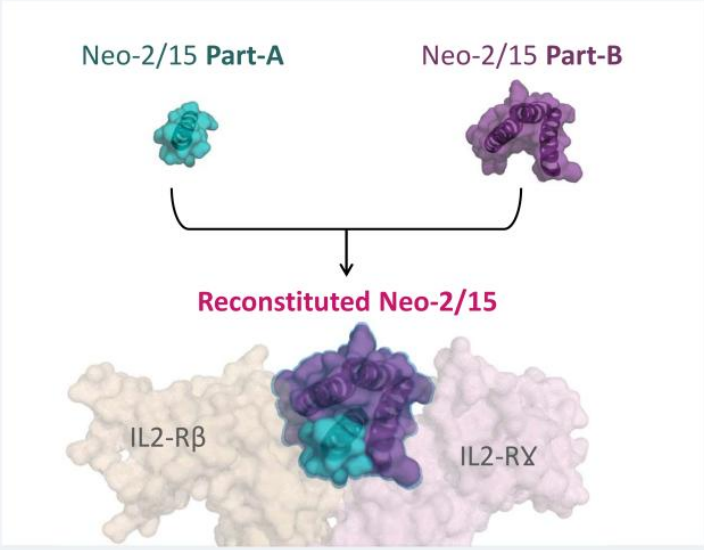
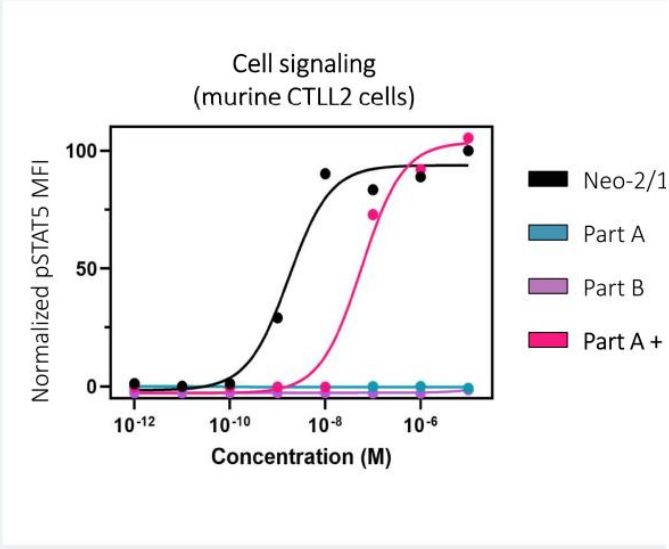
De Novo Split Technology: Conditionally Active IL-2 Mimetic





Quijano-Rubio et. al., AACR Virtual Annual Meeting II, Abstract #1075, Jun 2020

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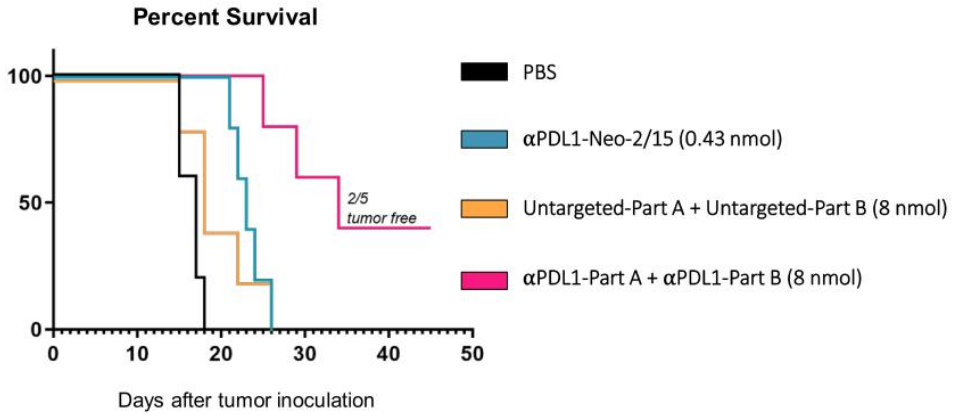
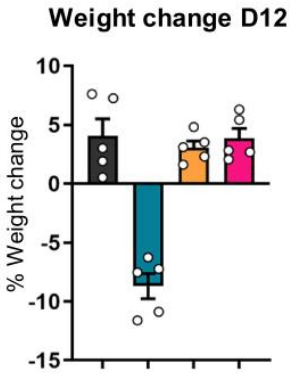
Targeted Split Neo-2/15 Increases Therapeutic Windo





- C57BL/6J mice bearing B16 PDL1Hi melanoma cells in flank
- All groups were co-treated biweekly with Ta99 mAb (150µg/mice)
- Targeted Neo-2/15 variants and Part-A fusions administered i.p.; Part-B fusions administered s.c. opposite flank of tumor

Quijano-Rubio et. al., AACR Virtual Annual Meeting II, Abstract #1075, Jun 2020

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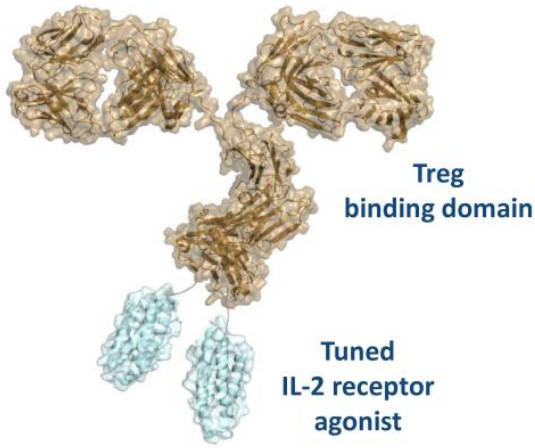
Highly Selective *De Novo* Treg Expander and Activator

- Highly tuned CD122/CD132 activator fused to Treg-targeting domain
- Potential to specifically expand Tregs for the treatment of autoimmune diseases and inflammation
- Finely tuned *de novo* protein to achieve optimal affinity and potency for specificity and cis-activation
- Demonstrated ability to drive specificity by targeting *de novo* cytokine mimetics
- Upcoming oral presentation at ASH on Dec. 12, 2022



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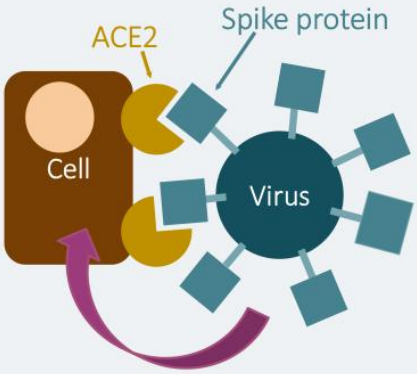
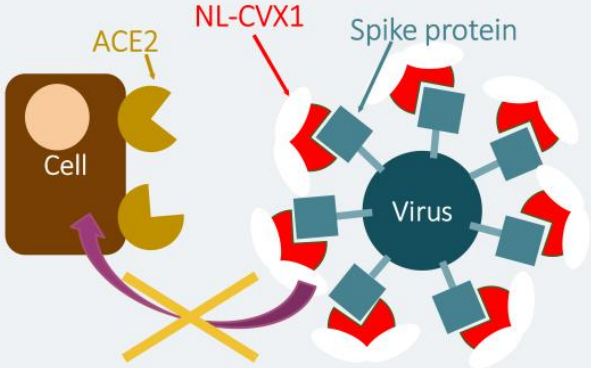
De Novo Platform Potential: COVID-19

SARS-CoV-2 uses **ACE2** as a receptor to gain access to and infect cells



NL-CVX1 - *de novo* ACE2 decoy:

- *Binds to SARS-CoV2 spike protein*
- *Inhibits viral infection in vitro*



De Novo protein designed, tested, and optimized in the pre-clinical setting in ~10 weeks

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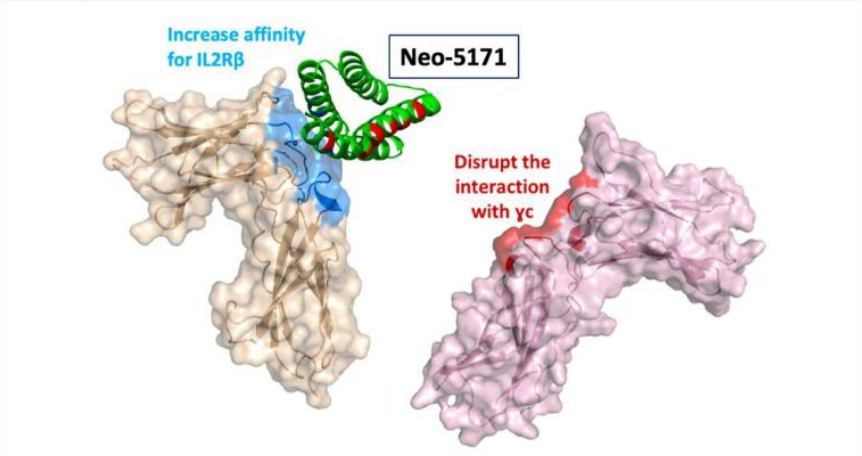
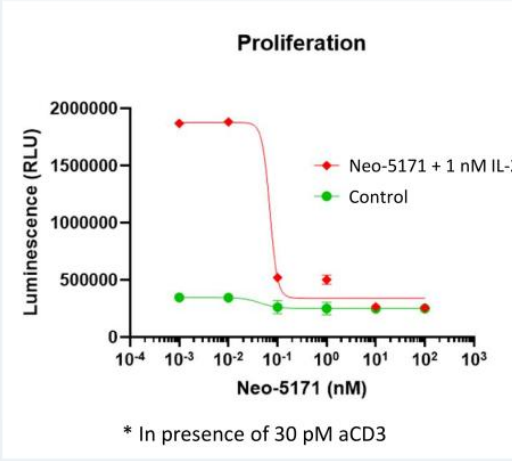
Neo-5171: A computationally designed *de novo* protein inhibitor of IL-2 and IL-15 signaling





* In presence of 30 pM aCD3

- Potent inhibitor of CD8 T-cell proliferation and IFN-g production
- Resistant to proteases and low pH
- Less impact on T-regulatory cells

R. Swanson et. al. Am. Coll Rheum. (ACR) 2021; Abstract 1438, Nov 2021

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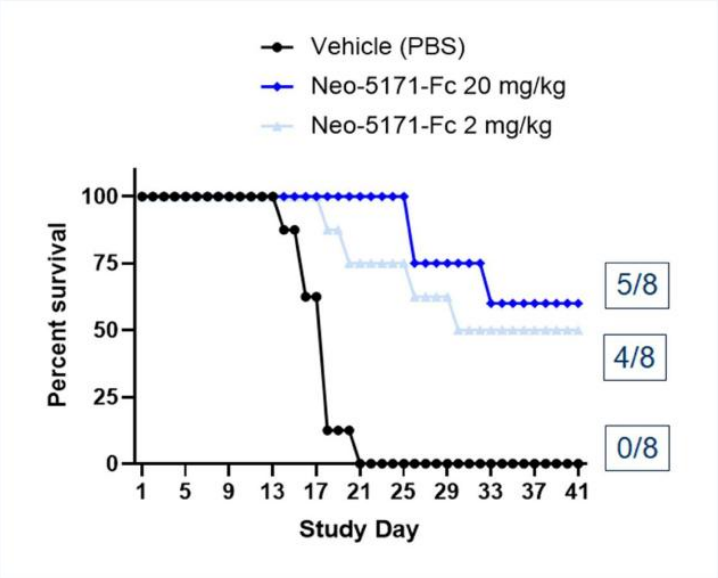
Neo-5171-Fc prolongs survival in a preclinical model o graft-vs-host disease (GVHD)



- Immunodeficient NSG mice were irradia received 10^7 human PBMC on Day -1
- Intraperitoneal dosing with Neo-5171-F q3d, beginning Day 0
- Mice were euthanized when experienci >20% body weight loss
- At high dose 62.5% of mice survived at study end (Day 42)

R. Swanson et. al. Am. Coll Rheum. (ACR) 2021; Abstract 1438, Nov 2021

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NL-201 Update

- In November 2022, we made a strategic decision to discontinue development of NL-201 and focus on advancing the next generation *de novo* protein therapeutics
- NL-201 Phase 1 experience demonstrates potential of using *de novo* proteins in humans
  - Demonstrated engagement of target receptors and expected pharmacodynamic changes
  - Preliminary data did not indicate significant risk of immunogenicity
- Based on a review of preliminary data, the expected benefit-to-risk ratio for patients, and recer developments in the field of IL-2 therapeutics, we determined that the resources required to continue development would be better applied to advancing the next generation of *de novo* protein therapeutics.

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Financial Highlights and Strategic Restructuring

Financial Highlights

- $106.9 million cash, cash equivalents, and short-term investments as of September 30, 2022
- Cash position expected to fund operations into the second half of 2025
- 42.6M common shares outstanding and 12.7M pre-funded warrants[1]

Strategic Restructuring

- Along with the decision to discontinue development of NL-201, we are implementing a restructuring plan that inclu a reduction in force of approximately 40%
- Cost savings as a result of this reduction in force as well as the discontinuation of development of NL-201 are expect to extend our cash runway into the second half of 2025

1. Warrants to purchase common shares 1:1 with an exercise price of $0.000001 as of September 30, 2022.

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Designing for life.

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