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):
June 17, 2024

Rani Therapeutics Holdings, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40672**	**86-3114789**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2051 Ringwood Avenue **San Jose, California**		**95131**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (408) 457-3700

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:

☐ 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
Class A common stock, par value $0.0001 per share	RANI	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 1.01 Entry into a Material Definitive Agreement.

Collaboration Agreement

On June 17, 2024, Rani Therapeutics, LLC, an operating subsidiary of Rani Therapeutics Holdings, Inc. ("Rani"), and ProGen Co., Ltd. ("ProGen") entered into a Collaboration Agreement (the "Collaboration Agreement"). Under the Collaboration Agreement, Rani and ProGen will collaborate to manufacture, develop, seek regulatory approvals for and, if approved, commercialize a product (the "Product") combining ProGen's GLP-1/GLP-2 dual agonist compound, PG-102, and the RaniPill HC oral delivery device (the "Device") in the field of weight management (including without limitation obesity, weight reduction and weight maintenance) in humans (the "Collaboration").

In accordance with a development plan approved by both Rani and ProGen, the parties will share responsibility for the development of the Product for weight management worldwide, with Rani leading such development for preclinical activities through Phase 1 clinical trials. After initiation of the first Phase 2 clinical trial of the Product, Rani will lead development of the Product in the United States, Canada, Europe (including the United Kingdom) and Australia and ProGen will lead development in all other countries. Rani and ProGen will prioritize seeking regulatory approvals for and, if approved, commercializing the Product in the United States, the European Union, the United Kingdom, Canada, Australia, Japan and South Korea. Rani and ProGen each hold the exclusive right to commercialize and sublicense the Product in their assigned territories.

Unless otherwise determined by the Collaboration Agreement, ProGen will be solely responsible for manufacturing and supplying PG-102 for all development and commercialization of the Product worldwide, and Rani shall be solely responsible for manufacturing and supplying the Product (the Device, and incorporating PG-102 into the Device) for all development and commercialization of the Product worldwide. Development costs, as well as operating profits and losses from the commercialization of the Product, will be equally shared by Rani and ProGen.

Under the Collaboration Agreement, Rani and ProGen each granted to the other party an exclusive right and license (except with respect to the other party's affiliates and sublicensees) to certain intellectual property to develop the Product for weight management and an exclusive right and license to seek regulatory approval for, and to use, sell, offer to sell, import and commercialize the Product in their assigned territories.

Each party has the right to opt-out of the Collaboration ("Opt-Out") at any time upon prior written notice to the other party. Following an Opt-Out, the continuing party shall have sole right to develop, conduct regulatory activities for and commercialize the Product on a worldwide basis. The Opt-Out party shall share all development costs and operating profit (or loss) through the effective date of the Opt-Out, and all costs to complete the conduct of any clinical trials of Product that have been initiated prior to delivery of the Opt-Out notice, even if the costs are incurred or the trials are completed after the effective date of the Opt-Out. The continuing party shall pay to the Opt-Out party low single to mid-single digit royalties on net sales of the Product made after the Opt-Out date depending on when the Opt-Out occurs.

The Collaboration Agreement contains customary representations, warranties and covenants, and mutual indemnification provisions. Under the Collaboration Agreement, the parties have certain rights to terminate for material breach, insolvency or safety concerns regarding the Product.

The description of the Collaboration Agreement contained herein does not purport to be complete and is qualified in its entirety by reference to the complete text of the Collaboration Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024.

Item 8.01 Other Events.

The Company is making available a copy of a presentation (the "Presentation") that the Company intends to use during a conference call and webcast scheduled to be held at 5 am Pacific Time on June 24, 2024 related to the Collaboration Agreement. A copy of the Presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Presentation dated June 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Date: June 24, 2024

Rani Therapeutics Holdings, Inc.

By: /s/ Svai Sanford
Svai Sanford
Chief Financial Officer

Exhibit 99.1

Rani Therapeutics and ProGen Collaboration

June 24, 2024

Rani Forward-Looking Statements

This presentation and the accompanying oral statements contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 as contained in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act, including statements regarding collaboration between Rani Therapeutics Holdings, Inc. ("Rani," "we," "us," or "our") and ProGen Co., Ltd., estimated obesity market size, product development and clinical trials, product potential of oral biologics, including RT-114, the regulatory environment, certain business strategies, capital resources, or operating performance. Forward-looking statements are based on information available at the time those statements are made or on management's good faith beliefs and assumptions as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in, or suggested by, the forward-looking statements. These risks and uncertainties include our future financial performance, including risks inherent in the preclinical and clinical development process and the regulatory approval process, the risks and uncertainties in commercialization and gaining market acceptance, the commercial potential of oral biologics including RT-114, our ability to complete development of the RaniPill® HC or any redesign and conduct additional preclinical and clinical studies of the RaniPill® HC or any future design of the RaniPill® to accommodate higher target payloads, the risks associated with protecting and defending our patents or other proprietary rights, the risk that our proprietary rights may be insufficient to protect our product candidates, the risk that we will be unable to obtain necessary capital when needed on acceptable terms or at all, our ability to enter into strategic partnerships and to achieve the potential benefits of such partnerships, including our collaboration with ProGen Co., Ltd., competition from other products or procedures, our reliance on third-parties to conduct our clinical and non-clinical trials, non-clinical and any future commercial supplies of our product candidates, our expectations regarding customer demand for our product candidates, increased regulatory requirements and other factors that are set forth in our filings with the Securities and Exchange Commission ("SEC"), including under the caption "Risk Factors" in our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q, and our other public filings made with the SEC and available at www.sec.gov.

Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "could," "estimate," "expect," "may," "potential," "should," "primed," "opportunity," or "target," or the negative of these terms or other comparable terminology. You should not put undue reliance on any forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved, if at all. Except as required by law, Rani does not undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

This presentation and the accompanying oral statements contain statistical data, estimates and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. This information involves many assumptions and limitations, and you are cautioned not to give undue weight to such information. We have not independently verified the accuracy or completeness of the information contained in the industry publications and other publicly available information. Accordingly, we make no representations as to the accuracy or completeness of that information nor do we undertake to update such information after the date of this presentation.

ProGen Disclaimer

This presentation and the accompanying oral statements contain forward-looking statements that are based on the current expectations and beliefs of ProGen Co., Ltd. ("ProGen"). This presentation and the accompanying oral statements regarding matters that are not historical facts, including, but not limited to, statements relating to the potential for clinical efficacy, potency, and tolerability of ProGen's products; the potential for conducting and successfully completing clinical trials, translation of preclinical and non-human data to the clinical and human contexts, obtaining favorable trial results, conducting later-phase trials, obtaining regulatory approval of product candidates for sale, successfully commercializing product candidates, and improving the treatment for more patients; the types of diseases that might be treated by ProGen products; the successful prediction of patient responses and efficacious doses; and the preferability of ProGen products to others available are forward-looking statements. These forward-looking statements are based on management's expectations and assumptions as of the date of such statements and are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, the uncertainty of success in research and development activities; risks related to clinical trials, including potential delays, safety issues, or negative results; competition from alternative therapies; the risk that ProGen may not be able to maintain and enforce its intellectual property; the risk that product candidates may not be successfully commercialized or adopted; the availability of financing; and risks related to the recruitment and retention of key employees, fluctuating markets and economic conditions, health care reform, prices, and reimbursement rates. The forward-looking statements in this presentation and the accompanying oral statements speak only as of the date of such statements, and ProGen undertakes no obligation to update or revise any of the statements. ProGen cautions investors not to place considerable reliance on the forward-looking statements contained in this presentation and the accompanying oral statements.

Today's Agenda

01 Rani Therapeutics and Progen Introduction & Deal Overview

02 Obesity Strategy

03 Overview of Rani's Technology Platform

04 Overview of PG-102

05 RT-114 / RPG-102 (Obesity)

06 Q&A

Presenters

Talat Imran

- Chief Executive Officer, Rani Therapeutics
- >15 years experience in Healthcare
- Venture capitalist for several Silicon Valley healthcare funds

Jong Gyun Kim, PhD

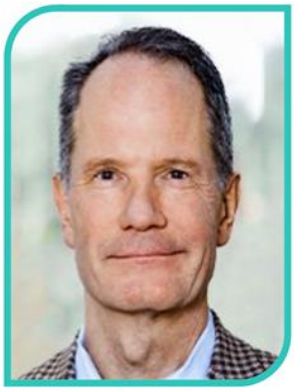
- Chief Executive Officer, ProGen
- >30 years of extensive experience in pharmaceutical industry
- R&D and strategic planning for drug development across multiple therapeutic areas

Rani THERAPEUTICS

ProGen

Leadership Team

Mir Hashim, PhD
- Chief Scientific Officer, Rani Therapeutics



Jesper Høiland,
- Strategic Advisor, Rani Therapeutics

Kyung-Hwa Son, PhD
- Chief Development Officer, Progen

Sae Won Kim, PhD
- Chief Scientific Officer, Progen

Rani THERAPEUTICS

Our mission at Rani is to end painful injections for the millions of patients suffering from chronic diseases

Rani Therapeutics NASDAQ: RANI	**Clinical-stage biotech focused on Oral Delivery of Biologic Drugs with Bioavailability Comparable to Parenteral Products**
TECHNOLOGY:	**RaniPill** • 200 µL Capacity (20-40mgs*) • Liquid Drug Formulation
PIPELINE:	**Programs across a variety of high value indications, including obesity, psoriasis, and osteoporosis**
DISCOVERY:	**Broad applicability across Nanobodies, Hemophilia, Bispecific MABs, Fertility, Genetic Medicine**
IP:	**472 Granted Patents and Pending Applications, 262 Granted Patents****

Rani THERAPEUTICS

*Dependent on drug concentration
** As of May 4, 2024

Rani's Strategic Vision in the 50 / 50 Partnership with ProGen

Rani THERAPEUTICS | RaniPill + ProGen | PG-102 *GLP-1/GLP-2*

Drug-agnostic oral delivery platform for biologics	Long-acting Fc fusion platform for multivalent agonists
Differentiated oral delivery mechanism, with bioavailability comparable to SubQ injection	Differentiated anti-obesity mechanism, with preclinical data showing improved body composition compared with Tirzepatide
Clinically demonstrated equivalent PD to SubQ delivery of GLP-1 through Rani route of administration – at the same dose	Clinically demonstrated favorable safety and differential PK profiles
Versatile delivery platform with broad applicability to address significant opportunities across large market indications in immunology, endocrinology, and beyond	Versatile metabolic benefits with broad applicability to address significant opportunities across broad market indications including T2D, MAFLD/MASH and CVD

Deal Rationale:

- ✓ **Targeting optimized delivery + optimized therapeutic**
- ✓ **Differentiated oral, low dose, convenient once-weekly GLP-1 / GLP-2 agonist, with potential to preserve lean mass & improve nutrient absorption**
- ✓ **Validating preclinical and clinical data**

Rani / ProGen Deal Structure

Rani and ProGen have entered into a collaboration agreement for the development and commercialization of a RaniPill capsule containing PG-102 (GLP-1 / GLP-2 dual agonist) for weight management (including obesity).

Deal Structure

- **No upfront payment**
- Co-Development Deal
- 50/50 WW revenue and cost share
- Development initially focused on major markets

Commercial Rights

- Rani holds exclusive rights to commercialize in the US, Europe, UK, Canada and Australia
- ProGen holds exclusive rights to commercialize in rest of world
- Each party has the right to sublicense within its territories

Manufacturing

- ProGen manufactures the drug substance
- Rani manufactures the drug product

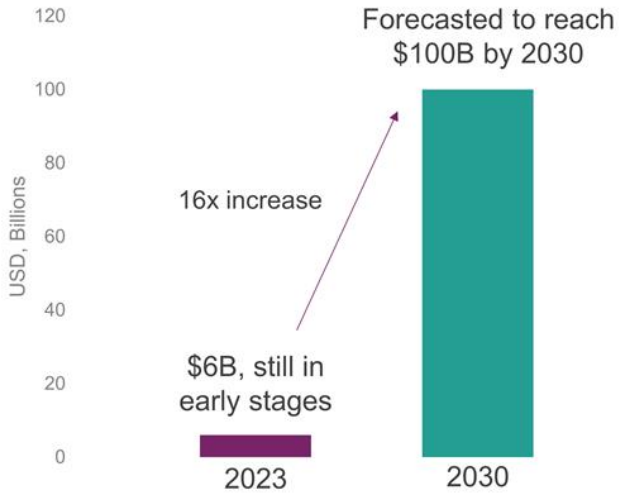
Rani THERAPEUTICS

ProGen

Obesity Strategy

Obesity is a Fast-Growing Market; Potential for Oral Options to Play an Important Role

Anti-Obesity Medications Market *



Across various therapeutic areas, patients prefer daily pill over current injection regimen **

64%-88% of patients with injection regimens of daily to every 6 months

* *Why the anti-obesity drug market could grow to $100 billion by 2030*, Goldman Sachs published 30 Oct 2023

** Data aggregated from two third-party surveys commissioned by Rani of U.S. patients (in 2017 for Humira and basal insulin and 2021 for other products). Patients surveyed (n=1,689) were aged 18 years or older and presently used one of Prolia, Humira, basal insulin, Stelara, Cosentyx, Entyvio, Simponi, or Evenity as an injectable biologic to treat a condition.

Rani THERAPEUTICS

ProGen

RaniPill Delivery Technology May Solve for the Shortcomings of Current Orals in Development

Low Bioavailability	High API Cost & Supply Chain Issues	Restrictive Administration Requirements	Inconvenient Dosing Regimen	Tolerability Risk
Oral chemistry-based formulations demonstrate ***bioavailability as low as <1%*** [1]	*Extremely high doses to reach therapeutic effectiveness* ▪ Novo's Oral semaglutide **350mg** per week vs Wegovy **2.4 mg** injectable dose (145x higher dose) [2] ▪ Novo's Oral amycretin and Viking's oral GLP-1/GIP may require **280-350 mg of API/week** to compete [3]	*Restrictive pre-treatment requirements can impact efficacy and patient adherence* ▪ Rybelsus (oral semaglutide) patients instructed to take drug **in fasted state** as it may increase absorption [4] ▪ Rybelsus clinical success rate 67% [5]	*BID or daily dosing often required to reach therapeutic serum concentrations*	*Twice-daily Danuglipron (small molecule)* ***discontinued*** *due to* ***tolerability issues*** *and* ***discontinuation rates*** [6]

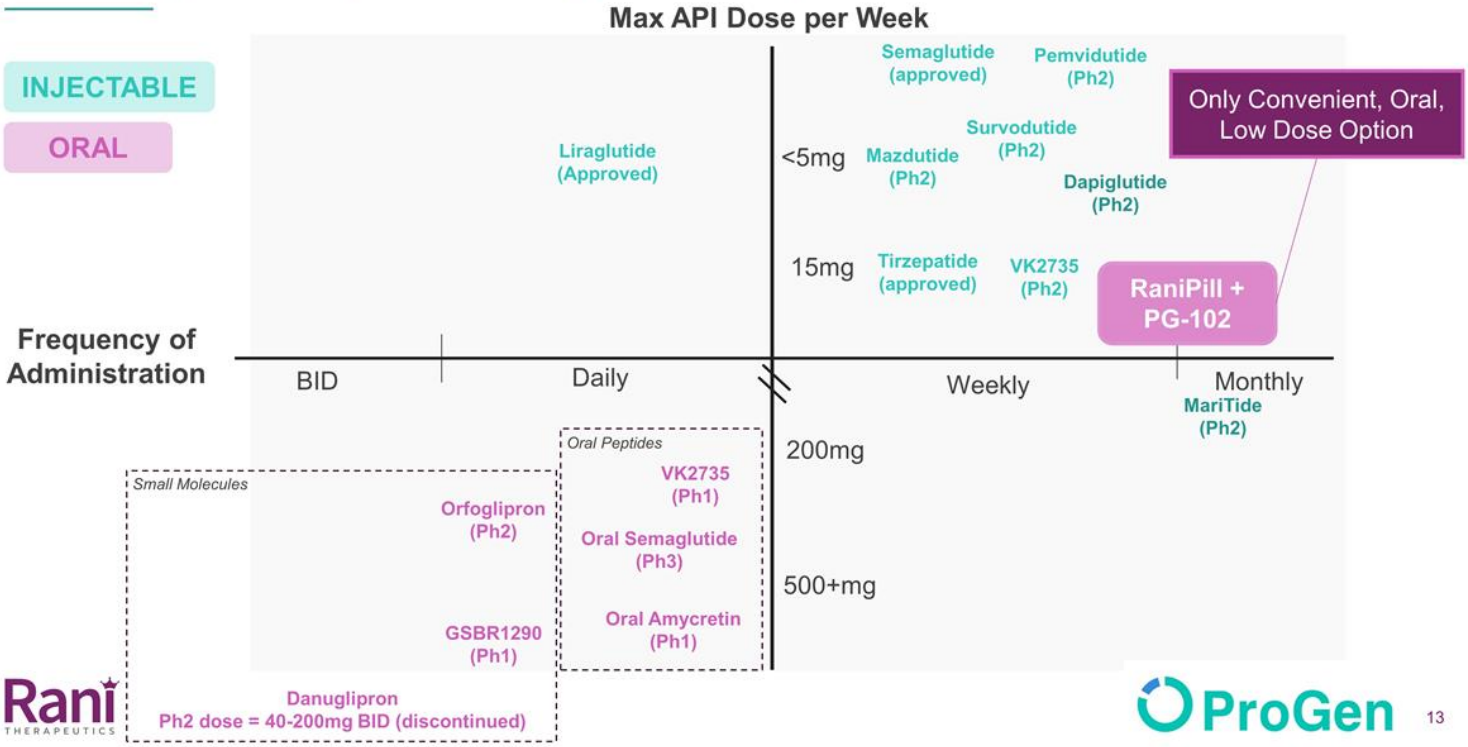
RaniPill **Potential Advantages**

✓ Significantly better bioavailability than other oral biologic technologies	✓ Significantly less API amount and cost needed than current orals in development	✓ No evidence of food effect so may avoid restrictive administration requirements	✓ Can dose infrequently compared to other orals (weekly or monthly)	✓ Can dose more frequently than SC to limit tolerability issues

Rani THERAPEUTICS

ProGen

Clear Opportunity in Obesity Landscape for RT-114/RPG-102 [7]



Overview of Rani's Technology Platform

RaniPill Development Progress and Safety

Preclinical

15 Molecules Assessed

antibodies, peptides, and large proteins delivered with high bioavailability

>7000 Capsules

tested *in vitro & in vivo*

60-Day GLP Study

completed with no clinical findings

Clinical

3 Phase 1 Studies*

completed

233 RaniPill Capsules

administered to 146 humans

7-Day Repeat Dose Study

completed

* As of 3/1/24; clinical studies with solid-dosage form

Well-Tolerated with No Serious Adverse Events Observed in Clinical Studies Completed to Date

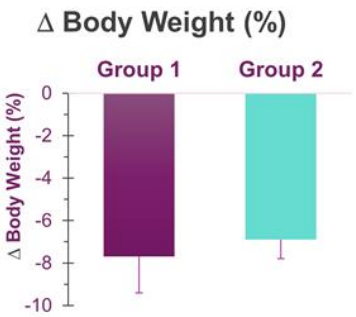
Demonstrated Equivalent PD to SC through Rani Route of Administration – *At Same Dose*

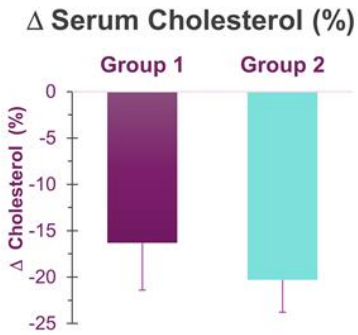
Objective
- To evaluate the PK-PD profiles of Triagonist (a unimolecular incretin agonist for GLP-1, GIP and Glucagon receptors) in Beagle dogs delivered SC or via endoscopically guided transenteric injection (to mimic the Rani route of administration)

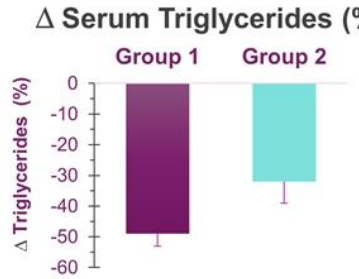
Subjects
- Beagles, adult male, 11 - 13 kg, Total N=10

Test Groups
- Group 1 Transenteric (N=5): Triagonist, 0.12mg/kg (0.05ml/kg) injected via endoscopic access
- Group 2 SC (N=5): Triagonist, 0.12mg/kg (0.04ml/kg) injected subcutaneously

Protocol
- All animals were dosed after an overnight fast
- Over 2 weeks, fasted body weights were taken, and blood samples were serially collected for tracking serum drug concentrations and various PD & safety biomarkers







Group 1: Endoscopic
Group 2: SC

All data are Means ± SE

Rani THERAPEUTICS

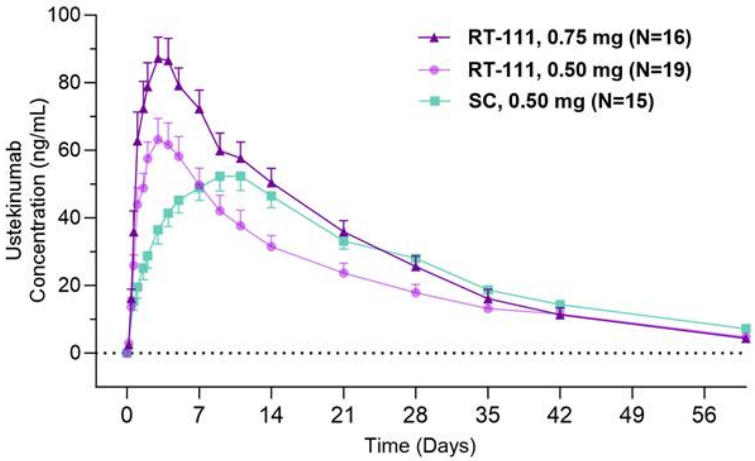
Data from preclinical study conducted by Rani using third party triagonist molecule

Rani Has Demonstrated Bioavailability Comparable to Subcutaneous Injection in Preclinical and Clinical Studies

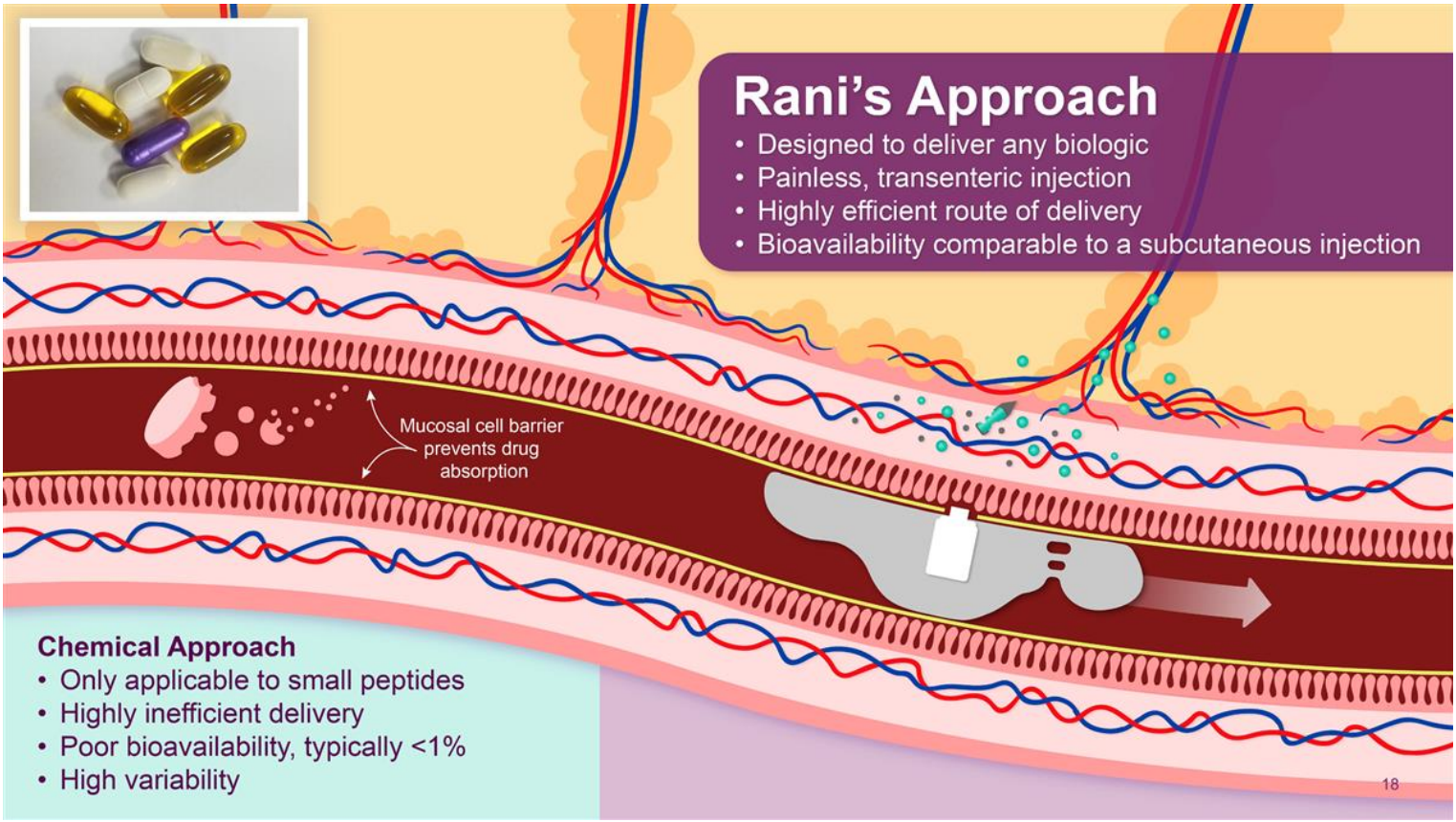
Biotherapeutic	Mean RaniPill Relative Bioavailability Compared to SC*
Ustekinumab Biosimilar	**91-159%**
Dupilumab	**89-102%**
Adalimumab Biosimilar	**93-103%**
FSH alpha/Gonal-F	**110-146%**
Exenatide	**80%**

* Data from preclinical head-to-head studies conducted by Rani.

PK Profiles of Single Doses of RT-111 (Oral Ustekinumab Biosimilar) vs SC Stelara® Injection



Data shown are Mean ± SE,
SC = Subcutaneous injection


Rani's Approach
• Designed to deliver any biologic
• Painless, transenteric injection
• Highly efficient route of delivery
• Bioavailability comparable to a subcutaneous injection
Mucosal cell barrier prevents drug absorption
Chemical Approach
• Only applicable to small peptides
• Highly inefficient delivery
• Poor bioavailability, typically <1%
• High variability
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Overview of PG-102

ProGen

Our Mission at Progen is to Improve Patients' Quality of Life with Longer-acting Protein Therapeutics

Progen **KONEX: 296160**	**Clinical-stage Biotech Company Developing Next Generation Long-acting, Multi-specific Fusion Protein Therapeutics**

TECHNOLOGY:

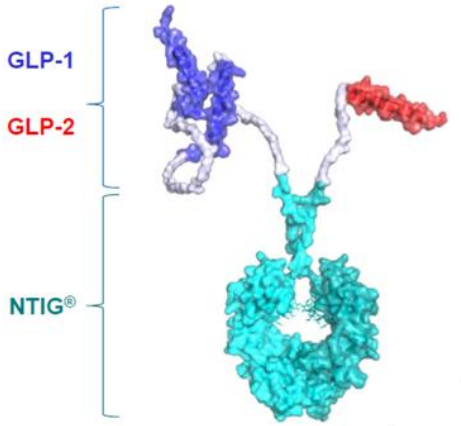
NTIG®
(Neo Tri-ImmunoGlobulin)

- **Multi-specific Fc fusion protein**
- **Long-acting injectables**

PIPELINE:

- **PG-102 for Obesity & T2D (Phase 1)**
- **Bispecific ADCs for Autoimmune diseases & cancer**

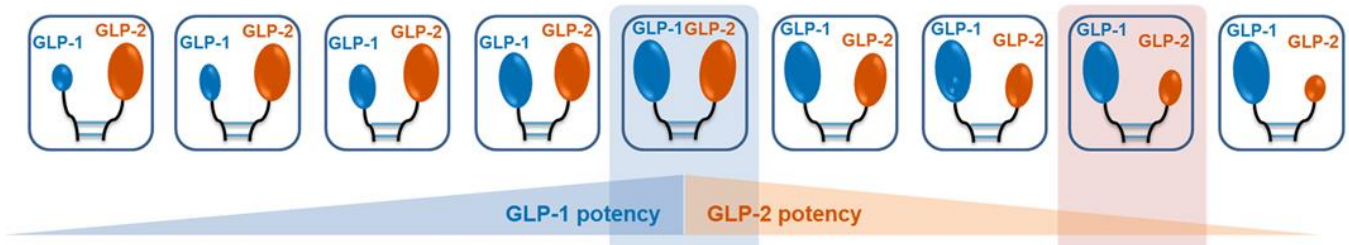
PG-102: Long Acting, Bispecific GLP-1/GLP-2 Dual Agonist for the Treatment of Obesity



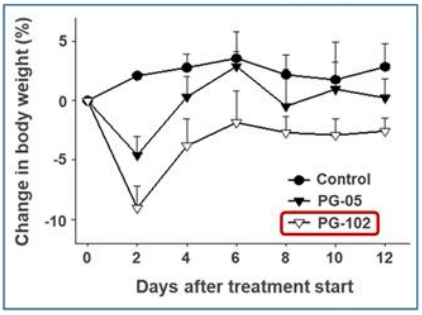
- Bispecific GLP-1/GLP-2, with optimized ratio biased toward GLP-1
- Heterodimeric Fc Fusion Protein
- Prolonged Half-Life

PG-102: An Experimentally-optimized, **Biased Agonist**

Biased agonism provided better weight management & glycemic control



Normal mouse model (Q2D, SC)



Source: 1. Kim ER et al., Hepatology. 2022 Jun;75(6):1523-1538 .
Q2D=once every 2 days; SC=subcutaneous

Phase 1a SAD Results Show Good Tolerability

Target Population	Healthy Subject
Administration	Single
Dosing Regimen	PG-102 vs Placebo
Primary Endpoint	Safety / Tolerability / PK
N=	8 Subjects per Group

Safety and Tolerability are a main concern with metabolic therapies due to high discontinuation rates

Summary of treatment-emergent adverse events (during 28-day period, Phase 1 SAD)

TEAEs	PG-102				
	Placebo	5 mg	15 mg	30 mg	60mg
Decreased appetite	0	0	1 (12.5%)	2 (25%)	2 (25%)
Nausea	0	0	0	0	3 (37.5%)
Diarrhea	1 (12.5%)	0	0	0	0
Vomiting	0	0	0	0	1 (12.5%)
Dyspepsia	0	1 (12.5%)	0	2 (25%)	2 (25%)
Constipation	1 (12.5%)	0	0	1 (12.5%)	0

ProGen

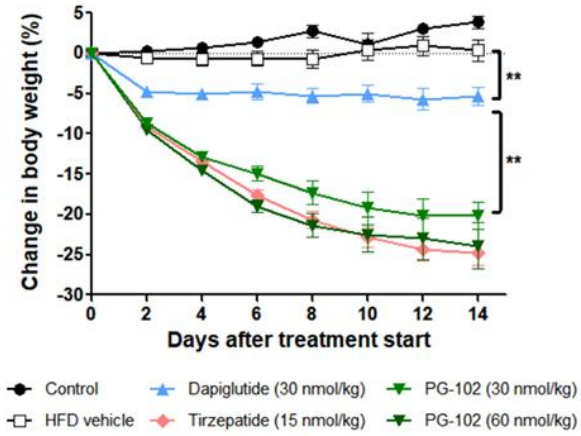
Potentially No Need to Titrate to High Dose

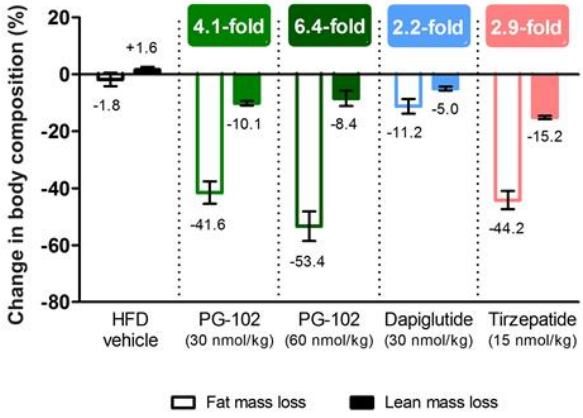
RT-114 / RPG-102 (Obesity)

Differentiation, Dosing and Development

PG-102 Reduces Body Weight & Improves Body Composition (DIO mice)

Improvement of body composition (fat vs. lean mass loss), under similar weight loss condition (vs. Tirzepatide)

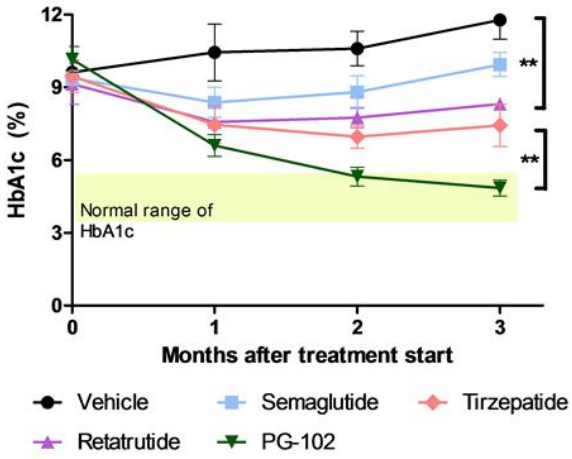




**p<0.01. Data are shown in ±SEM.
DIO=diet-induced obesity; HFD=high fat diet; SEM=standard error of the mean; VAT=visceral adipose tissue; SAT=subcutaneous adipose tissue
Source: Timothy Oh et al., The Effect of Bispecific GLP-1R/GLP-2R Agonist Compared with Dual GLP-1R/GLP-2R Agonist and Dual GLP-1R/GIPR Diet-Induced Obesity Mouse Model. Presentation at the 83rd ADA Annual Meeting.; †Jastreboff AM et al., N Engl J Med. 2022 Jul 21;387(3):205-216

PG-102 Demonstrated Greater Glycemic Control vs Semaglutide, Tirzepatide and Retatrutide (*db/db* mice)

At the same dosage level (30 nmol/kg), PG-102 exerts greater glycemic control than semaglutide, tirzepatide and retatrutide

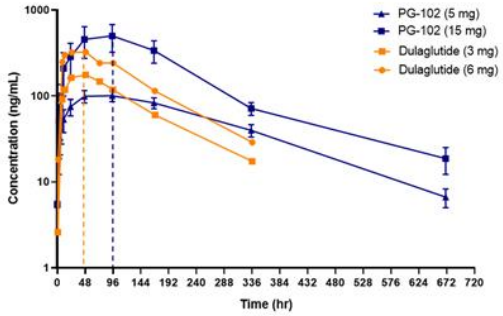


**p<0.01. Data are shown in ±SEM.
Source: Sae Won Kim et al., PG-102, a bivalent GLP-1R/GLP-2R agonist, protects b-cell mass and enhances glycemic control in obese db/db mice, showing superiority over semaglutide, tirzepatide, and retatrutide. Presentation at the 84th ADA Annual Meeting

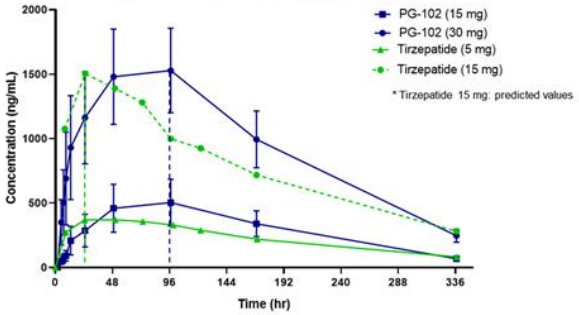
PG-102: Pharmacokinetic Profile

PG-102 shows longer T_{max} & higher AUC_{last} → Tolerability & persistence ↑

PK profile (PG-102 vs Dulaglutide[1])



PK profile (PG-102 vs Tirzepatide[2])

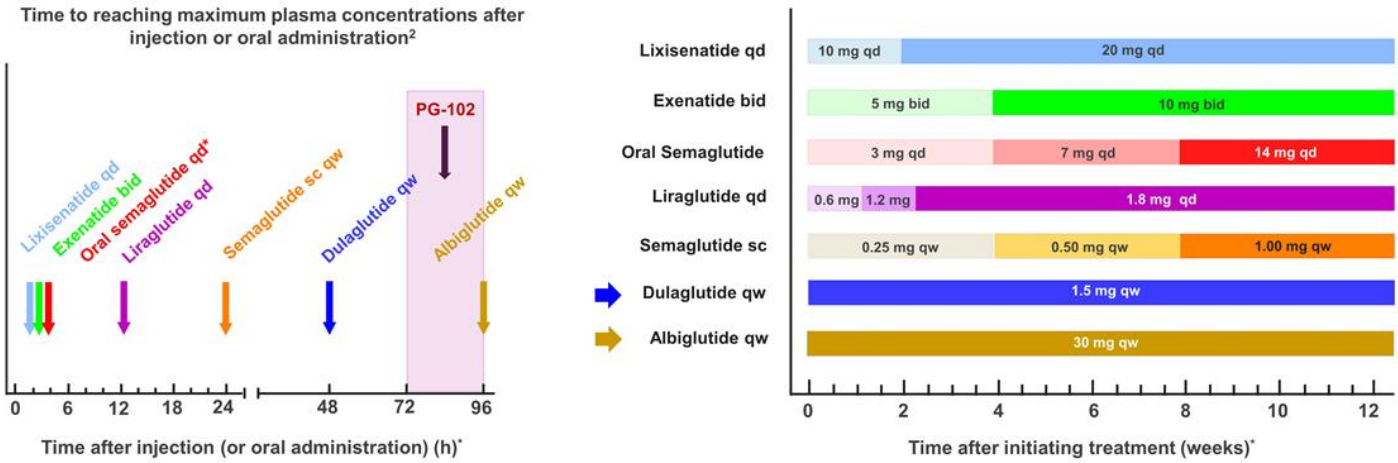


ProGen

Poster presentation at the 84th ADA Annual Meeting (June 21-24, 2024, Orlando).
1859-LB: PG-102, a novel bispecific GLP-1R/GLP-2R Fc-fused agonist—Data on safety, tolerability, and pharmacokinetics (PK) in single ascending dose trial in healthy subjects
1. . FDA review: Clinical Pharmacology and Biopharmaceutics Review(s): 125469Orig1s000. 2. Center for Drug Evaluation and Research Application Number: 215866Orig1s000, Clinical Pharmacology Reviews.

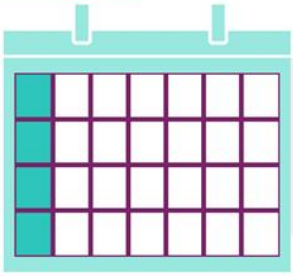
Association between T_{max} & Up-titration

Long T_{max} may obviate need of up-titration



* Nauck MA et al. Mol Metab. 2021 Apr:46:101102.
BID=twice a day; qd=once daily; qw=once weekly

RT-114/RPG-102 Target Dosing



Once a Week Oral Dosing

Potential for Monthly Dosing

Total of *52* *pills per year per patient*

Key Benefits Targeted:

- No painful injections
- Potential for better tolerability with more frequent, smaller doses than injectable
  - ➢ Tighter banding of serum concentrations
- Potential for less frequent administration than oral competitors
  - ➢ Other orals expected to require daily or BID dosing
- Potentially no dose titration required
- Less API required compared to chemistry based oral approach

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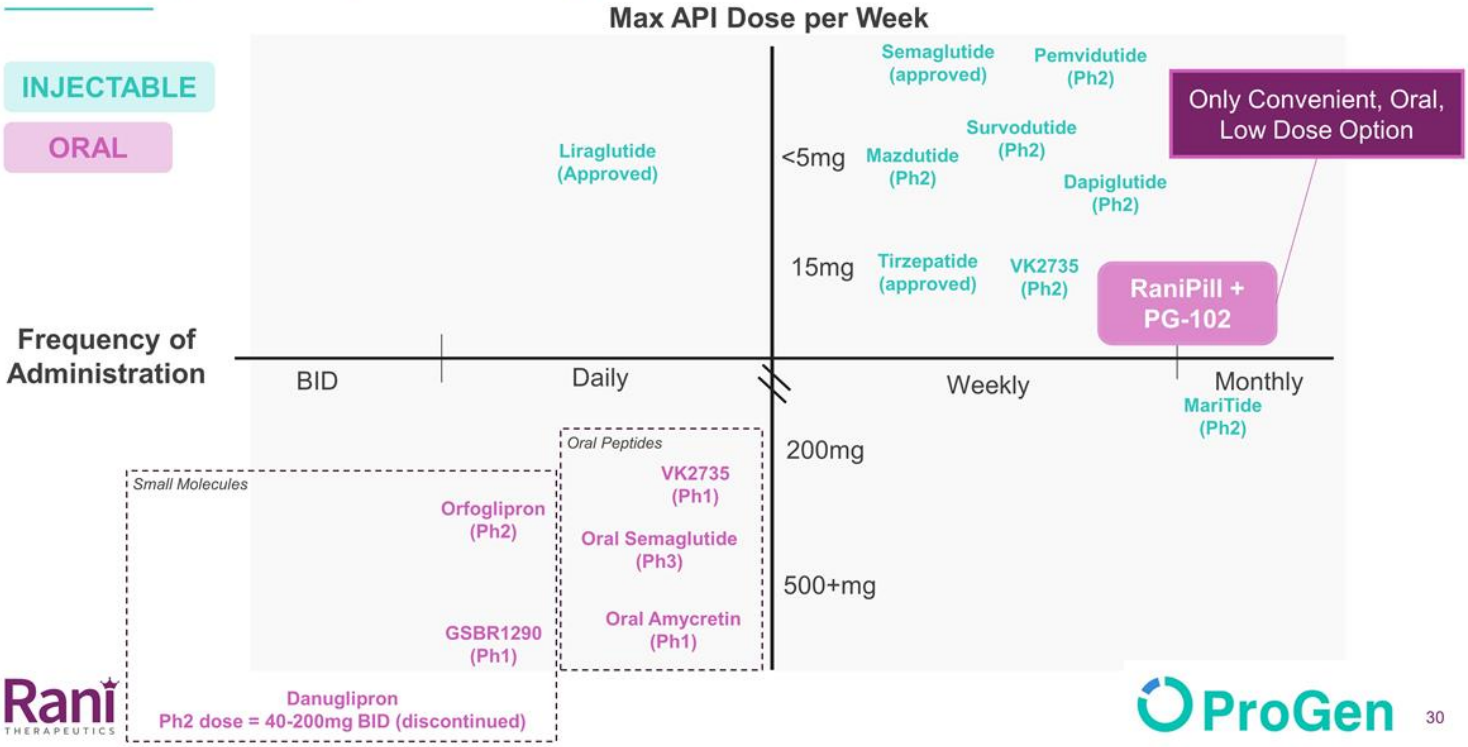
Clear Opportunity in Obesity Landscape for RT-114/RPG-102 [7]



Expected Clinical Development Timeline for RT-114/RPG-102

2025 | 2026

Phase 1A and 1C

Study Phase	1A	1C
Study Population	HV (BMI 18-30 kg/m^2)	Obese (non-diabetic) (BMI 30-39.9 kg/m^2)
Sample Size	30	40
Design	Open-label	Open-label
Objective(s)	▪ Safety (TEAEs & SAEs) ▪ PK ▪ BA ▪ PD marker	▪ Safety (TEAEs & SAEs) ▪ PK ▪ PD (% change in BW, lipids, glucose, insulin, C-peptide, glucagon)
Dose group(s)	▪ RaniPill 15 mg (N=10) ▪ RaniPill 30 mg (N=10) ▪ SC Injection 15 mg (N=10)	▪ Placebo (N=15) QW ▪ RaniPill XX mg (N=15) QW ▪ RaniPill XX mg (N=15) QM/Q2W
Treatment period (F/U)	Single ascending dose - 4 weeks F/U	Repeat Doses 4-7 weeks - 4 weeks F/U
Study duration	4-5 months	6-9 months

Phase 2a Obesity (12 weeks treatment)

*XX - Doses TBD based on ProGen Data and discussion

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Potential Differentiation of RT-114/RPG-102

Efficacy

- Potential greater fat mass loss & less lean mass loss than competitors
- Potential for improved nutrient absorption and nutritional status

Safety

- Potential less GI side effects (nausea, vomiting, diarrhea)
- Eliminate injection site reactions
- Reduce risk of off-target effects compared to oral small molecules
- Potential to improve tolerability without needing to titrate dosing

Convenience

- Long-acting and oral dosing
- Potential for weekly or monthly dosing
- Do not anticipate food impact or mealtime restrictions

COGS

- Less API required than chemistry-based oral options due to similar bioavailability to SC injections
- Expect competitive commercial COGS

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ProGen


Q&A

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[1] Rybelsus U.S. prescribing information, *Pharmacokinetics*.

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[3] For oral amycretin, *Novo Nordisk's oral amycretin outshines Wegovy in early obesity study*, Anna Bratulic, FirstWord PHARMA, 07 Mar 2024. For VK2735 oral, *Viking Therapeutics Announces Results from Phase 1 Clinical Trial of Oral Tablet Formulation of Dual GLP-1/GIP Receptor Agonist VK2735*, Viking Therapeutics press release, 26 Mar 2024.

[4] Rybelsus U.S. prescribing information, I*ndications and Usage*.

[5] Granhall et al, Clinical Pharmacokinetics (2019) 58:781–791 2019. In single dose study of oral semaglutide, highest percentage of subjects with measurable semaglutide plasma concentrations among dose groups was 66.7% (16/24).

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[7] For Danuglipuron, *Pfizer Announces Topline Phase 2b Results of Oral GLP-1R Agonist, Danuglipron, in Adults with Obesity*, Pfizer press release, 01 Dec 2023. For VK2735 subcutaneous, Viking Therapeutics Announces Positive Top-Line Results from Phase 2 VENTURE Trial of Dual GLP-1/GIP Receptor Agonist VK2735 in Patients with Obesity, Viking Therapeutics press release, 27 Feb 2024. For VK2735 oral, *Viking Therapeutics Announces Results from Phase 1 Clinical Trial of Oral Tablet Formulation of Dual GLP-1/GIP Receptor Agonist VK2735*, Viking Therapeutics press release, 26 Mar 2024. For oral amycretin, *Novo Nordisk's oral amycretin outshines Wegovy in early obesity study*, Anna Bratulic, FirstWord PHARMA, 07 Mar 2024. For Orfoglipron, *Daily Oral GLP-1 Receptor Agonist Orfoglipron for Adults with Obesity*, N Engl J Med 2023; 389:877-888, 23 Jun 2023. For Mazdutide, *A phase 2 randomised controlled trial of mazdutide in Chinese overweight adults or adults with obesity*, Linong Ji, Nature Communications, 14 Dec 2023. For Survodutide, *Glucagon and GLP-1 receptor dual agonist survodutide for obesity: a randomised, double-blind, placebo-controlled, dose-finding phase 2 trial*, Prof Carel W. le Roux, The Lancet, 05 Feb 2024. For liraglutide, see Victoza U.S. prescribing information, *Dosage and Administration*. For oral semaglutide, *Oral semaglutide 50 mg taken once per day in adults with overweight or obesity (OASIS 1): a randomised, double-blind, placebo-controlled, phase 3 trial*, Prof Filip K Knop, MD, The Lancet, 25 Jun 2023. For Dapiglutide, *Dapiglutide, a Once-Weekly GLP-1R/GLP-2R Dual Agonist, Was Safe and Well Tolerated and Showed Dose-Dependent Body Weight Loss over Four Weeks in Healthy Subjects*, Minna B. Olsen, Diabetes, 01 Jun 2022. For MariTide, Amgen's obesity drug takes the weight off and may keep it off, too, early data suggest, Helen Floersh, FierceBiotech, 7 Feb 2024. For semaglutide (approved), see Wegovy U.S. prescribing information, *Dosage and Administration*. For pemvidutide, Altimmune Announces Positive Topline Results From MOMENTUM 48-Week Phase 2 Obesity Trial Of Pemvidutide, Altimmune press release, 30 Nov 2023. For Tirzepatide, see Zepbound U.S. prescribing information, *Dosage and Administration*. For GSBR1290, *Structure Therapeutics Announces Positive Results from Phase 1b Clinical Study of Oral GLP-1 Receptor Agonist GSBR-1290 and Provides Program Update*, Structure Therapeutics press release 29 Sep 2023.