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): August 28, 2024

KRYSTAL BIOTECH, INC.

(Exact name of registrant as specified in its charter)

82-1080209 (IRS Employer Identification Number)

Delaware (State or other jurisdiction of incorporation)

001-38210 (Commission File Number) 2100 Wharton Street, Suite 701

Pittsburgh, Pennsylvania 15203 (Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (412) 586-5830

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)

Derecommencement 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	KRYS	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company \Box

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On August 28, 2024, Jeune Aesthetics, Inc. (the "Company"), a wholly owned subsidiary of Krystal Biotech, Inc., issued a press release announcing phase 1 (PEARL-1) positive interim safety and efficacy results for KB301 in the treatment of lateral canthal lines and dynamic wrinkles of the décolleté. In addition, the press release indicated that the Company and Krystal Biotech, Inc. would host a conference call and webcast at 4:30 p.m. ET on August 28, 2024, to discuss the PEARL-1 Cohort 3 and Cohort 4 interim results, the KB301 clinical development program, the Company's pipeline product candidates, and the strategic vision for the Company. For purposes of the call and webcast, the Company provided a slide presentation, which is available on the "Investors" section of Krystal Biotech, Inc.'s website at www.krystalbio.com. Copies of the press release and the slide presentation are attached hereto as Exhibit 99.1 and Exhibit 99.2, respectively, and are incorporated by reference herein.

The information in this Item 7.01 of this Current Report on Form 8-K and in Exhibits 99.1 and 99.2 attached hereto shall not be (i) deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, or (ii) incorporated into any registration statement or other document filed with the Securities and Exchange Commission by Krystal Biotech, Inc., 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
- 991
- Press Release dated August 28, 2024 Slide Presentation dated August 2024 99.2
- 104 Cover Page Interactive Data file (embedded within the Inline XBRL document)

SIGNATURES

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 hereunto duly authorized.

Date: August 28, 2024

KRYSTAL BIOTECH, INC.

By: Name: Title: /s/ Krish S. Krishnan Krish S. Krishnan Chairman and Chief Executive Officer



Jeune Aesthetics Announces Phase 1 Positive Interim Safety and Efficacy Results for KB301 in the Treatment of Lateral Canthal Lines and Dynamic Wrinkles of the Décolleté

Décolleté indication selected for Phase 2 study expected to start next year

Conference call to discuss results scheduled for Wednesday, August 28, 2024 at 4:30 p.m. ET

PITTSBURGH, August 28, 2024 (GLOBE NEWSWIRE) – <u>Jeune Aesthetics, Inc.</u> ("Jeune"), a wholly owned subsidiary of <u>Krystal Biotech, Inc.</u> ("Krystal") (NASDAQ: KRYS) leveraging Krystal's clinically validated gene-delivery platform to fundamentally address – and reverse – the biology of aging skin, announced today positive interim safety and efficacy results from both Cohorts 3 and 4 of PEARL-1, a Phase 1 study evaluating KB301, an investigational aesthetic treatment designed to deliver the *COL3A1* transgene and increase type III collagen ("COL3") levels in the skin, for the improvement of lateral canthal lines at rest in Cohort 3 and for the improvement of dynamic wrinkles of the décolleté in Cohort 4.

"Today's injectable aesthetics toolbox is limited to toxins and fillers which allow us to manipulate, but not rejuvenate, aging skin," said Steve G. Yoelin, M.D., one of the principal investigators for PEARL-1. "With its unique mechanism of action and compelling early efficacy data, I am excited by the potential for KB301 to change the treatment paradigm in the field of medical aesthetics and meet the growing demand for treatments that fundamentally replenish the skin or delay signs of aging."

Meaningful and sustained improvements in skin aesthetic attributes, assessed using a Global Aesthetic Improvement Scale ("GAIS"), were reported by the study investigators and subjects alike in both the décolleté and lateral canthal regions. Increased subject satisfaction with wrinkle appearance was also reported using a Subject Satisfaction Questionnaire ("SSQ").

Dynamic Wrinkles of the Décolleté Topline Efficacy Results

A total of 20 subjects were enrolled. Two subjects dropped out before completing KB301 treatments. The remaining 18 subjects were assessed for aesthetic improvement out to two months following KB301 injections in the décolleté region. Results included:

- Study investigators reported clinically meaningful improvement in wrinkles both one and two months after treatment, as assessed by GAIS:
 - At two months: 94% of subjects had at least a one point improvement and 28% had a two point improvement - the maximum potential score on the GAIS scale.
 - At one month: 83% of subjects had at least a one point improvement and 28% had a two point improvement.

- Subjects also reported improvements in wrinkles that increased from the first to second follow up month, as assessed by GAIS:
 - At two months: 89% of subjects reported at least a one point improvement and 39% reported a two point improvement.
 - At one month: 61% of subjects reported at least a one point improvement and 28% reported a two point improvement.
- 94% of subjects reported improved satisfaction with their wrinkles' appearance two months after treatment, as assessed by SSQ.
- Improvements were also seen across multiple additional skin attributes, as assessed by GAIS, including crepiness, hydration, and radiance, for which investigators reported improvements of 1 point or better in 89%, 94%, and 94% of subjects, respectively, two months after treatment.

Lateral Canthal Line Topline Efficacy Results

A total of 13 subjects were enrolled. One subject dropped out before completing KB301 treatments. The remaining 12 subjects were assessed for aesthetic improvement out to two months following KB301 injections in the lateral canthal region. Results included:

- Study investigators again reported clinically meaningful improvement in wrinkles both one and two months after treatment, as assessed by GAIS:
 - At two months: 75% of subjects had at least a one point improvement and 50% had a two point improvement.
 - At one month: 92% of subjects had at least a one point improvement and 50% had a two point improvement.
- Subjects also reported improvements in wrinkles, as assessed by GAIS:
 - At two months: 50% of subjects reported at least a one point improvement and 25% reported a two point improvement.
 - At one month: 58% of subjects reported at least a one point improvement and 17% reported a two point improvement.
- 67% of subjects reported improved satisfaction with their wrinkles' appearance two months after treatment, as assessed by SSQ.
- Improvements across multiple additional skin attributes were again reported, as
 assessed by GAIS, with investigators reporting one point or greater improvements in at
 least 75% of subjects for each of crepiness, hydration, and radiance, two months
 following treatment.

Across both cohorts, the KB301 safety profile was consistent with prior clinical experience in Cohorts 1 and 2 and other injectable aesthetic products. Adverse events were primarily

injection associated, mild-to-moderate, and transient. No drug related serious adverse events were reported.

"We are excited to share today's data update in which we continue to see profound aesthetic benefits following KB301 administration in both the lateral canthal region and the décolleté, in line with our earlier findings from PEARL-1 Cohort 2," said September Riharb, Senior Vice President of Jeune. "We are also pleased that, in addition to reporting improvements in fine lines and wrinkles, both study investigators and subjects alike reported high rates of improvement across a variety of key skin attributes, consistent with KB301's paradigm-changing mechanism of delivering *COL3A1* directly to the skin and restoring COL3 levels to more youthful levels. The natural looking results of KB301 rejuvenated skin are exactly what consumers are looking for today. On the basis of the strong results we saw in Cohort 4, we will be progressing KB301 into Phase 2 development for the treatment of dynamic wrinkles of the décolleté, a priority aesthetic site for which no FDA-approved injectables exist, and will be meeting with the FDA in the coming months to enable initiation of the Phase 2 study."

A subset of Cohort 4 subjects opted in to redose at the two month follow up timepoint, after completing the assessments described above. Additional data collection is ongoing in the redosed subjects. Upon completion, detailed results of PEARL-1 Cohorts 3 and 4 will be presented at future scientific conference(s).

Conference Call, Webcast and Presentation Information

Jeune and Krystal will host a conference call and webcast today, Wednesday, August 28, 2024, at 4:30 pm ET, to discuss the PEARL-1 Cohort 3 and Cohort 4 interim results, the KB301 clinical development program, Jeune's pipeline product candidates, and the strategic vision for Jeune.

Investors and the general public can access the live webcast at: https://www.webcaster4.com/Webcast/Page/3018/51166

For those unable to listen to the live webcast, a replay will be available on the Investor's section of the Krystal website at www.krystalbio.com.

About KB301

KB301 is an investigational aesthetic therapy employing Krystal's novel replication-defective, non-integrating HSV-1-based vector to deliver two copies of the *COL3A1* transgene and increase COL3 levels in skin to address signs of skin aging associated with declining collagen levels and damage of the skin's extracellular matrix. KB301 is formulated as a solution for direct intradermal injection to aesthetic priority areas.

About the PEARL-1 Study

PEARL-1 is a multi-cohort Phase 1 study designed to evaluate the safety, tolerability, initial efficacy and duration of effect of intradermal KB301 injections in adult subjects. Previously disclosed results from Cohorts 1 and 2 revealed that repeat administration of KB301 to various

locations on the body was well-tolerated and, in 2022, Jeune announced positive proof-ofconcept, safety, efficacy, and nine-month durability data from PEARL-1 Cohort 2 with respect to improvement of fine lines and wrinkles. Building on the results from Cohort 2, Cohorts 3 and 4 of PEARL-1 are open-label, single-arm cohorts designed to evaluate KB301 in two potential target indications for Phase 2, lateral canthal lines at rest and dynamic wrinkles of the décolleté. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.

About Jeune Aesthetics, Inc.

Jeune Aesthetics, Inc., a wholly-owned subsidiary of Krystal Biotech, Inc., is a biotechnology company leveraging a clinically validated gene-delivery platform to fundamentally address – and reverse – the biology of aging skin. For more information, please visit http://www.jeuneinc.com.

About Krystal Biotech, Inc.

Krystal Biotech, Inc. (NASDAQ: KRYS) is a commercial-stage biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs. VYJUVEK[®] is the Company's first commercial product, the first-ever redosable gene therapy, and the first medicine approved by the FDA for the treatment of dystrophic epidermolysis bullosa. The Company is rapidly advancing a robust preclinical and clinical pipeline of investigational genetic medicines in respiratory, oncology, dermatology, ophthalmology, and aesthetics. Krystal Biotech is headquartered in Pittsburgh, Pennsylvania. For more information, please visit <u>http://www.krystalbio.com</u>, and follow @KrystalBiotech on <u>LinkedIn</u> and <u>X</u> (formerly Twitter).

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Krystal Biotech, Inc., or its wholly-owned subsidiary, Jeune Aesthetics, Inc., including statements about the clinical utility of KB301; the potential for KB301 to change the treatment paradigm in the field of medical aesthetics and meet the growing demand for treatments that fundamentally replenish the skin or delay signs of aging; Krystal's and Jeune's plans to progress KB301 into Phase 2 development for the treatment of dynamic wrinkles of the décolleté, including timing of meeting with the FDA and the initiation of the Phase 2 study; Krystal's proprietary, HSV-1 based gene delivery platform; and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forwardlooking statements as a result of various important factors, including: uncertainties associated with regulatory review of clinical trials, the availability or commercial potential of KB301, and such other important factors as are set forth under the caption "Risk Factors" in Krystal's annual and quarterly reports on file with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Krystal's and Jeune's views as of the date of this press release. Krystal and Jeune anticipate that subsequent events and developments will cause their views to change. However, while Krystal and Jeune may elect to

update these forward-looking statements at some point in the future, they specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing Krystal's and Jeune's views as of any date subsequent to the date of this press release.

CONTACT

Investors and Media: Stéphane Paquette, PhD Krystal Biotech spaquette@krystalbio.com

JEUNE

Revolutionizing Aesthetic Medicine

Exhibit 99.2

KB301 PEARL-1 Interim Results for Dynamic Wrinkles of the Décolleté and Lateral Canthal Lines

August 2024

Forward-Looking Statements

This presentation, which includes the accompanying oral presentation, contains, and the answers to questions may contain, forward-looking statements that involve substantial risks and uncertainties. Any statements in this presentation about future expectations, plans and prospects for Jeune Aesthetics, Inc., a wholly-owned subsidiary of Krystal Biotech, Inc. (together, the "Company"), which may include but are not limited to statements about the clinical utility of KB301; the Company's plans for a Phase 2 study evaluating KB301 for the treatment of dynamic wrinkles of the décolleté, including the expected timing of initiation of the Phase 2 study; the markets for aesthetic skin conditions and the primary and secondary tools for treating aesthetic skin conditions, including existing consumer demand for aesthetic treatments and expected market expansion trends; the projected aesthetic treatment ladder; the potential market for aesthetic treatments for aged skin; the development and commercialization of the Company's pipeline product candidates, including conduct and timelines of clinical studies; the Company's technology platform; and other statements containing the words "anticipate", "believe", "estimate", "expect", "intend", "may", "plan", "predict", "project", "target", "potential", "likely", "would", "could", "could", "continue" and similar expressions, constitute forward-looking statements as a result of various important factors, including: uncertainties associated with regulatory reviews and clinical trials; the availability or commercial potential of the Company's products; and such other important factors as are set forth in the Krystal Biotech Inc.'s filings with the U.S. Securities and Exchange Commission. The forward-looking statements, it specifically disclaims any obligation to do so.

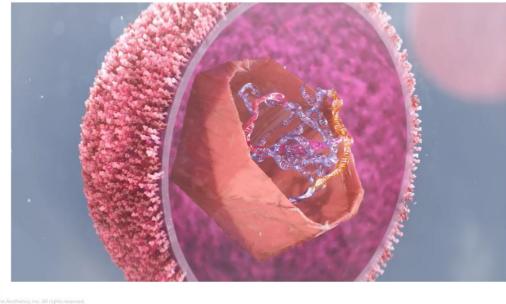
This presentation contains estimates and statistical data made by independent parties or the Company relating to, among other things, market size and growth. These estimates involve assumptions and limitations and should not be given undue weight. Neither the Company nor any other person makes any representation as to the accuracy or completeness of such estimates or data or undertakes any obligation to update such estimates or data. In addition, any projections, assumptions and estimates of the Company's future performance and the future performance of the markets in which the Company operates are necessarily subject to a high degree of uncertainty and risk. All product candidates described in this presentation are investigational treatments.

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Jeune Aesthetics: Wholly Owned Subsidiary of Krystal Biotech, Inc.

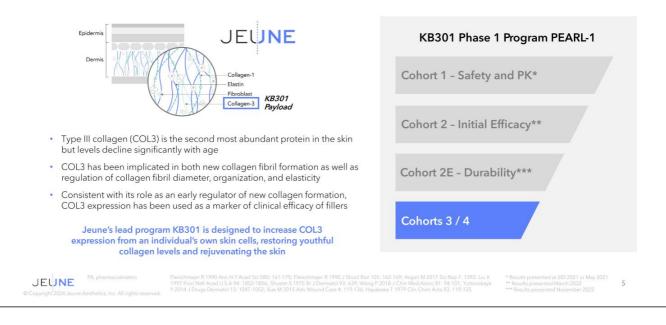
Fully integra	ted biotech developing portfolio of gen	etic medicines	
R&D	JEUNE Subsidiary Dedicated to Aesthetics and Cash Pay Markets* Clinical Development Commercial 	Regulatory	
Manufacturing		Legal	
© Copyright 2024 Jeune Aesthetics, Inc. All rights reserved.	Finance / HR	*Jeune holds exclusive license to Krystal's HSV-1 gene delivery platform for cash pay markets	3

Jeune's Groundbreaking Skin Rejuvenation Technology



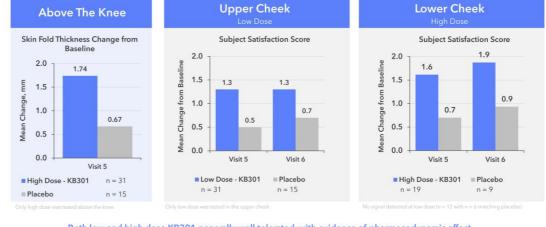
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Lead Program KB301 Designed to Increase Type III Collagen Levels in Aging Skin



Aesthetic Improvement Reported at All KB301 Treatment Sites in Cohort 2

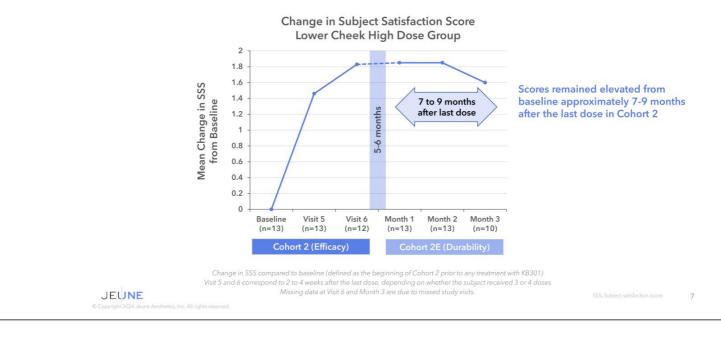
Cohort 2: Exploratory, 2:1 randomized, placebo-controlled study evaluating safety and efficacy of KB301, administered up to four times weekly, at either low and/or high dose, to the area above the knee, the lower cheek and upper cheek.



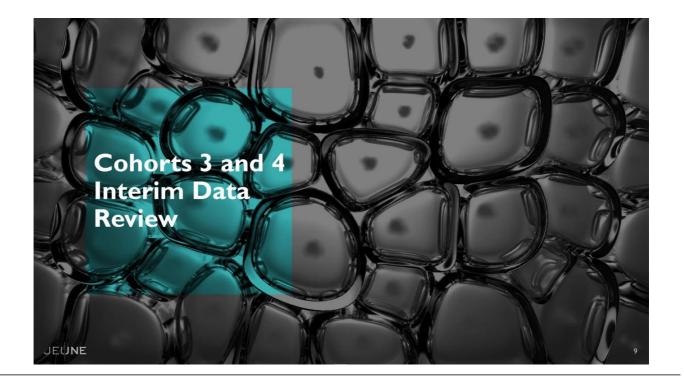
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Durability of at Least Nine Months Observed in Extension Follow Up







PEARL-I Cohort 3 Evaluating KB301 in Lateral Canthal Lines at Rest

Study Objective and Design

- Multicenter, open-label study evaluating KB301 for the improvement of lateral canthal lines at rest in adults
- Key study objectives were safety and preliminary efficacy as assessed by investigator and subject, as well as images; surveys for efficacy assessment included
- Investigator and Subject: 5-point Global Aesthetic Improvement Scale (GAIS)
- Subject Only: Subject Satisfaction Questionnaire (SSQ)
- Dosing and administration technique also explored as part of study
- Key exclusion / inclusion criteria
 - Adults up to 75 years of age, Fitzpatrick phototype score I-IV
 - No skin conditions or aesthetic treatments in lateral canthal region, last 6 months

Study Population

- 13 subjects enrolled and 12 assessed through two month follow up
 Assessed subjects:
 - Median 57 years of age (range = 31 to 68 years), 92% female
 - Six subjects received high dose KB301 with microneedling treatment
 - Two subjects received low dose KB301 and five subjects received high dose KB301 with standard syringe

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Abbreviated Treatment and Assessment Schedule for Interim Readout

Treatment Visits
 Image Capture Subject and Investigator Assessments Weekly Treatments
V One Month
One Month Follow Up
 Image Capture Subject and Investigator Assessments
🗸 One Month
Two Month Follow Up
 Image Capture Subject and Investigator Assessments

Interim Safety Findings in Lateral Canthal Region

Both low and high dose KB301 generally well tolerated with no adverse change in safety profile upon repeat dosing

	Grade 1	Grade 2	Grade 3	Grade 4
Dryness	2	0	0	0
Erosion	0	2	0	0
Itching	6	0	0	0
Pain	2	6	0	0
Swelling	13	21	0	0
Texture	2	0	0	0
N	25	29	0	0

Possibly related or related systemic AE reported in 2 subjects: headache, chills, muscle aches (n=1 each)

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*Total localized, possibly related or related AEs recorded over all visits and both right and left injection sites

Clear and Clinically Meaningful Improvements in Lateral Canthal Lines



GAIS Results for Wrinkles / Lines

Improvements Also Observed Across Multiple Other Skin Attributes



GAIS Responder Rates* by Attribute

Lateral Canthal Lines Before and After Images



Lateral Canthal Lines Before and After Images



PEARL-I Cohort 4 Evaluating KB301 in Dynamic Wrinkles of the Décolleté

Study Objective and Design

- Multicenter, open-label study evaluating KB301 for the improvement of dynamic wrinkles of the décolleté in adults
- Key study objectives were safety and preliminary efficacy as assessed by investigator and subject, as well as images; surveys for efficacy assessment included
 - Investigator and Subject: 5-point Global Aesthetic Improvement Scale (GAIS)
 - Subject Only: Subject Satisfaction Questionnaire (SSQ)
- Key exclusion / inclusion criteria
- Adults up to 75 years of age, Fitzpatrick phototype score I-IV
- No skin conditions or aesthetic treatments in décolleté region, last 6 months

Study Population

- 20 subjects enrolled and 18 assessed through two month follow up
- Assessed subjects:
 - * Median 60 years of age (range = 42 to 74 years), all female
 - All received high dose KB301 with standard syringe

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Abbreviated Treatment and Assessment Schedule for Interim Readout

Treatment Visits	
 Image Capture Subject and Investigator Assessments Weekly Treatments 	
🗸 One Month	
One Month Follow Up • Image Capture • Subject and Investigator Assessments	
🗸 🛛 One Month	
Two Month Follow Up Image Capture Subject and Investigator Assessments 	

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Interim Safety Findings in the Décolleté Region

	Grade 1	Grade 2	Grade 3	Grade 4
Bumps	14	1	0	0
Burning	1	0	0	0
Discomfort	0	1	0	0
Edema	1	0	0	0
Hypersensitivity	2	0	0	0
Itching	20	5	0	0
Pain	12	3	0	0
Redness	26	5	0	0
Swelling	2	3	0	0
Tenderness	12	0	0	0
Tightness	0	1	0	0
N	90	19	0	0

KB301 generally well tolerated with no adverse change in safety profile upon repeat dosing

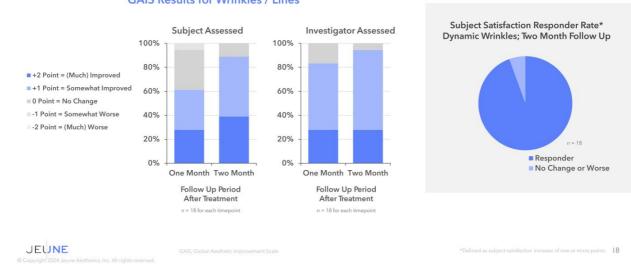
Possibly related or related systemic AE reported in 4 subjects: chills (n = 3), headache, muscle aches, dizziness, vomiting, swelling of hands (n=1 each)

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otal localized, possibly related or related AEs recorded over all visits 17

Profound Improvements Increasing With Time in the Décolleté

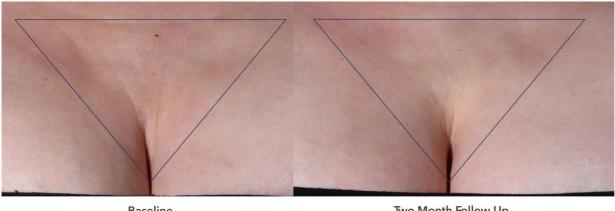


GAIS Results for Wrinkles / Lines

Again Seeing Improvements Across Multiple Other Skin Attributes



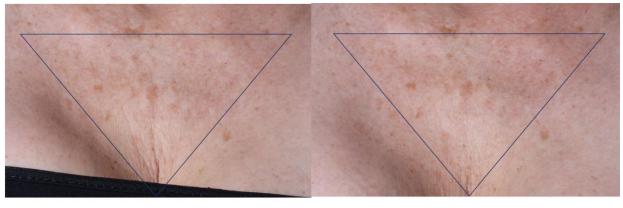
GAIS Responder Rates* by Attribute



Baseline

Two Month Follow Up

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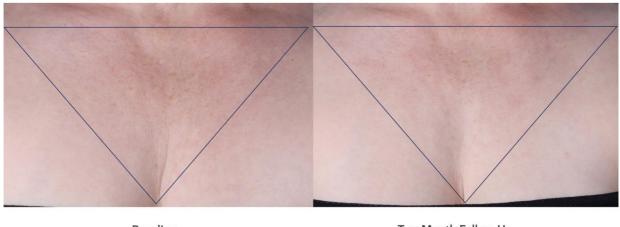


Baseline

Two Month Follow Up

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Décolleté Before and After Images



Baseline

Two Month Follow Up

JEUNE Opyright 2024 Jeune Aesthetics, Inc. All rights reserved.



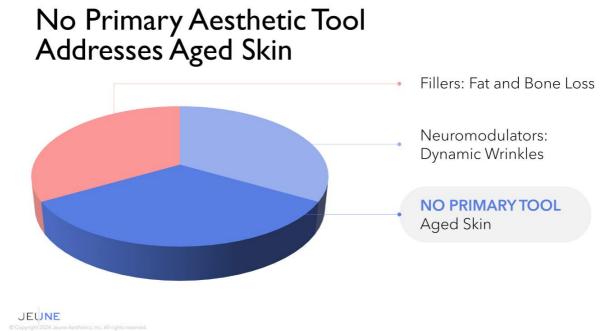
Next Steps for KB301

Select indication for Phase 2 development - *completed, décolleté selected*

Develop KB301-specific scale and assessment tool for patient report outcomes

□ Initiate Phase 2 development - *target study start 2025*

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Ideal Primary Tool for Skin Rejuvenation



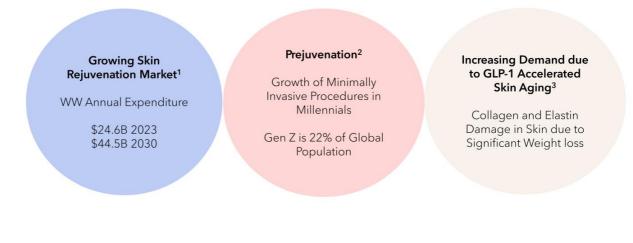
Significant Existing Consumer Demand



VOGUE The Décolleté: New Emphasis is Being Given to Keeping the Area as Fresh as your Face²

JELUNE 1 International Society of Plastic Surgery, Global Survey, 2022. Consumer number calculated from global neurotoxin procedures divided by two © Copyright 2024 Jeans Assthetics, Inc. All rights reserved.

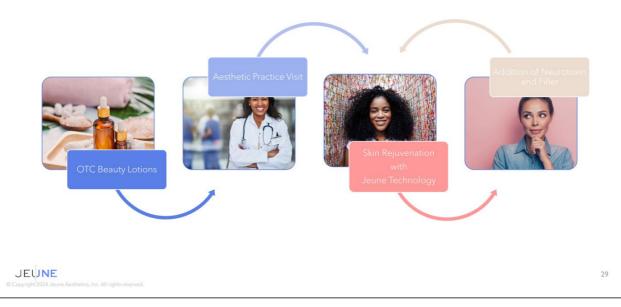
Significant Market Expansion Trends



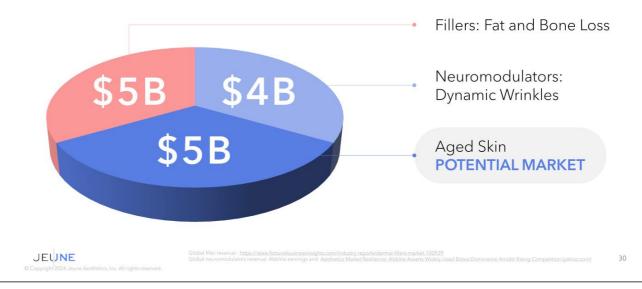
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Projected Aesthetic Treatment Ladder



Market Size



Deep Pipeline Targeting Priority Extracellular Matrix Proteins Including Elastin

PROGRAM	INDICATION	PAYLOAD	PRE-CLINICAL	PHASE 1	PHASE 2
KB301	Dynamic Wrinkles of the Décolleté	Type III collagen (COL3)			
KB303	TBD	elastin (ELN)			
KB304	TBD	COL3 + ELN			
KB302	TBD	Type 1 collagen (COL1)			
KB305	TBD	Type IV collagen (COL4)			

KB303 for the Delivery of Elastin



- ${\mbox{\circle*{1.5}}}$ Transduction and elastin secretion by skin cells in vitro
- Expression and elastin fiber formation confirmed in both young and aged mice treated with KB303
- KB304 combination vector is also in advanced preclinical development

KB303 Treated Mouse Skin



Long Term Strategic Vision for Jeune

- Krystal well-positioned to rapidly advance KB301 through value-creating Phase 2 milestones
- As KB301 progresses in the clinic, need for dedicated resource and commercial aesthetics expertise will grow
- Jeune was purpose-built as wholly owned subsidiary to allow optionality for spin-out or partnership during clinical development

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Vision: Creating a new segment of fundamentally rejuvenative aesthetics built on Krystal's proprietary gene delivery platform

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