

Company Introduction



July 2023



Cautionary Statement

This presentation contains forward-looking statements that involve risks and uncertainties. These statements are only predictions and are based on our current expectations. There are risks, uncertainties, and other factors that could affect the accuracy of these statements, including those inherent in the process of discovering, developing, and commercializing products for use in humans. Our actual results could differ materially from those expressed or implied by these forward-looking statements. The forward-looking statements included in this presentation represent our views as of the date on the cover. We do not expect to update any of these forward-looking statements or to conform these statements to actual results. We cannot assure you of the accuracy or completeness of the data included in this presentation. Market data and industry statistics contained in this presentation are included based on information available to us that we believe is materially accurate. Forward-looking information obtained from these sources, including estimates of future market size and revenue, are subject to the same qualifications and the additional uncertainties accompanying any forward-looking statements. You should not place undue reliance on statements contained in this presentation.

Novel therapeutic platform to address fat malabsorption for Enteral Nutrition (EN) patients



Company overview

- Mission-oriented company focused on improving the lives of a largely pediatric patient population (average patient age is 12)
- Novel and proven therapeutic technology for enteral nutrition patients with fat malabsorption where no other adequate solutions exists
 - Variety of clinical use cases in disease states such as Cystic Fibrosis (CF), Short Bowel Syndrome (SBS), Oncology, Neonatal Intensive Care Unit (NICU) and wider Intensive Care Unit (ICU) settings
 - Strong clinical efficacy data in Cystic Fibrosis patients with robust safety profile
- First and only FDA-cleared (2015) digestive enzyme product designed for enteral nutrition with device and method-of-use patents providing broad protection for the platform out to 2036
- Rapid uptake within Cystic Fibrosis (~33% market share in 2022, up from ~4% in 2019) in past 4 years driven by broad payer access and favorable patient outcomes

Key performance indicators

\$65m+

Revenue 2023E

\$20m+

Adj. EBITDA 2023E ~30%

YoY revenue growth 2022A-2023E

~\$4.5bn1

Total addressable market across disease states

~\$150m^{1,2}

Total Cystic Fibrosis addressable market

~\$1.4bn^{1,2}

Total Short Bowel Syndrome addressable market

~33%

Cystic Fibrosis EN penetration in 2022

95%

of commercial lives have received authorization

~760k¹

Potential patients across six disease states

58
Total FTEs

Issued patents

~1k

Active patients

Management with significant experience across rare diseases



Daniel OrlandoChief Executive Officer
& Board Member

(since Jun-2019)

VERICEL





Jason WeinerChief Commercial
Officer

(since Jul-2020)

VERICEL





Chris Parrish Chief Operating Officer

(since Nov-2021)

VERICEL





Bill Scheinler Chief Legal & Compliance Officer

(since Apr-2016)







Dave Recker MDActing Chief Medical
Officer

(since 2022)

VERICEL



- Figures shown for US market only
- 2. Market size in 2027

Alcresta's journey – Alcresta continues to make strong progress to becoming a leading rare disease platform



Alcresta today

disease platform

Fully capitalized on the CF opportunity

Medium term

A leading rare

- **Established RELiZORB as the standard** of care for SBS patients on EN, based on clinical human data in the medium term
- Strong recognition among clinicians of RELiZORB's quality-of-life benefits for other disease states such as pancreatitis, oncology and in the ICU
- Continued innovation of the RELiZORB platform, with plans to pursue a neonatal intensive care unit-adapted device
- Fast growing rare disease platform with market leading expertise and capabilities in commercializing and **launching** rare disease products

Establishing Alcresta

2019 - 2022

- RELiZORB receives permanent Medicare billing code from Centers for Medicare & Medicaid Services in 2019
- Daniel Orlando (CEO 2019), Jason Weiner (CCO - 2020), and Chris Parrish (COO - 2021) join Alcresta
- Establishment of Alcresta's innovative patient access program
- RELiZORB added as a covered benefit for most payors

2022

Sales force doubled to 20 Account Managers in 2022

2023

- **Strong penetration within CF market** (~33% market share in 2022)
- 95% of commercial lives received authorization for RELiZORB
- Well-established, scalable rare disease platform, with proven commercialization model
- 2-pillar strategy to expand base business in CF and prepare for launch of next-generation RELiZORB device, **ALC-078**
- Positive initial feedback received from CFSAN on FCN submission, with commercial launch following full FDA clearance next year

Launch of RELiZORB in 2016

No Medicare billing code

in 2015

Alcresta established in 2011

2018

\$4m

Revenue

Launching RELiZORB

Pre-2019

FDA clearance for RELiZORB received

~\$13m Adj. EBITDA 2023



\$54m Revenue

High-growth rare disease GI platform with full commercial and operational capabilities delivering a ~30% EBITDA margin in 2023E



1	Novel and proven therapeutic technology	 First and only FDA-cleared digestive enzyme product designed for enteral nutrition RELiZORB has delivered improved clinical outcomes in fat malabsorption during enteral feeding and is SoC¹ in CF Significant clinical efficacy demonstrated across other disease states in a primarily pediatric patient pool Easy-to-use, in-line tube feeding, quick-connect design contributes to wide outpatient adoption Robust safety profile with significant impact on patient quality of life 		a andre P
2	Strong financial profile	 Historical revenue CAGR of ~44% from 2020A to 2022A, ~30% YoY revenue growth from 2022A to 2023E ~30% EBITDA margin 2023E to grow significantly as a result of high gross margins and operating leverage Profitable in 2021 and 2022 despite considerable investment in next-gen replacement product (ALC-078) 	~30% YoY revenue grow 2022A-23E	~30% th EBITDA margin 2023E
3	RELiZORB is indicated for fat malabsorption in enteral feeding	 RELiZORB label is tied to Enteral Nutrition rather than a disease state Successful penetration to date in the CF market increasing market share from 4% to 33% from 2019 to 2022 Significant white space remaining within Cystic Fibrosis addressable market despite status as standard of care Real-World Evidence is establishing utility in a range of critical need and rare disease populations beyond CF 	Payer Approved Outpatient Uses	Cystic Fibrosis Pancreatitis Other Short Bowel Syndrome Post Surgical Oncology
4	Near-term sizable SBS market expansion with Next- gen device (ALC-078)	 RELiZORB is being used by KOLs² in SBS despite being limited to continuous feeds and compatible formulas ALC-078 expands RELiZORB use to additional formulas/feeding modes common in SBS SBS TAM is ~9x larger than CF, usage per day is >2x CF - expected ALC-078 launch is 2024 ALC-078 510(k) includes strong SBS pre-clinical data and is low-risk, as it replaces the predicate RELiZORB 	~2k ³ Target CF patients	~8k ³ Target SBS patients
5	Innovative reimbursement model and broad payer access	 Unique and proven reimbursement model resulting in strong patient access and attractive reimbursement rate Distinct HCPCS⁴ Billing Code (B4105) enables easier billing and claims processing through limited SPP⁵ network A proven Rare Disease 3rd-party RELiZORB Support Services works with HCPs⁶, patients and pharmacies resulting in broad patient access, expanded medical policy and successful reimbursement 	>95% of commercial lives have received authorization	
6	Scalable operations and platform with robust 3rd-Party Supply Chain	 Current commercial platform and capabilities can scale to support RELiZORB expansion and additional products Modular manufacturing platforms designed to support scale up Blue-chip global supply chain partners with established long-term contracts Secure inventory with 2-year product shelf-life (anticipated 3-year shelf life for ALC-078) 	Outsourced manufacturing	
7	Considerable barriers to entry	 Broad patent protection out to 2036 (US, EU, Japan, Israel, other countries) Multiple patent families covering technologies beyond current RELiZORB product design Specialized product requiring proprietary know-how, specialized capabilities and unique formula 	71 Issued patents	74 Pending applications
8	Experienced, innovative management team with highly engaged employees	 Expertise in all critical operational functions needed to commercialize and launch rare disease products Existing salesforce call points already include targets for planned launch of ALC-078 Dynamic small company (FTEs = 58) culture with employee satisfaction measures far above peers⁷ 	27 Sales &	FTEs8 19 5 R&D/ Medical / Clinical

Notes:

- Standard of Care
- Key opinion leaders
- 3. Figures shown for US market only

- Healthcare Common Procedure Coding System
- . Specialty pharmacy provider
- Healthcare practitioners

- 7. Latest employee survey 91% Overall Employee Engagement
- 8. 7 additional employees in administrative, legal or management roles

Alcresta's novel technology, RELiZORB, is the Standard of Care¹ and only FDA-cleared solution for EN patients with fat malabsorption



Fat malabsorption represents a significant unmet need across multiple disease states

~760k patients within 6 disease states with significant unmet need associated with fat malabsorption on EN



EN is frequently used across a number of disease states where fat malabsorption is an issue



None of the currently available pancreatic enzyme replacement therapies (PERT) are formulated for, tested in, or indicated for use in patients receiving EN



Fat malabsorption results in weight loss, malnutrition, and developmental delay in children, and sometimes death

RELiZORB breaks down (hydrolyzes) fats in most enteral feeding tube formulas tested²

RELiZORB is a cartridge that utilizes Alcresta's proprietary approach, with lipase immobilized to beads which hydrolyzes fats outside the body



RELiZORB is designed to mimic the function of **human pancreatic lipase**, which is normally secreted by the pancreas

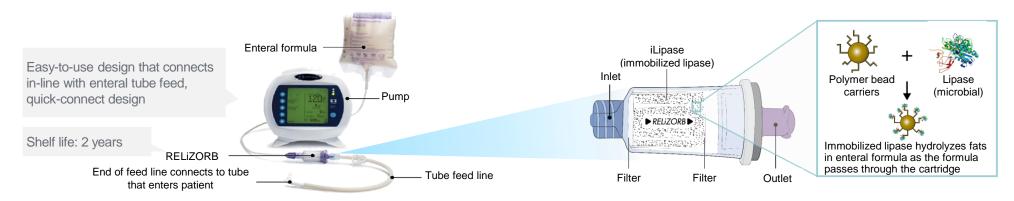


iLipase is the digestive enzyme lipase immobilized to polymeric microbead carriers



The patient ingests the enteral formula containing **broken-down fats** while the **iLipase remains in the cartridge** and is not ingested

RELiZORB is a digestive enzyme cartridge that contains iLipase



Notes:

- For Cystic Fibrosi
- 2. Based on broad selection of enteral formulas used in a variety of different disease states

Clear value proposition to patients and clinicians, with desirable clinical outcomes, quality-of-life improvements, and robust safety profile



Normalized fat absorption in 24-hrs

The 497 Study¹

The 497 study is a 24-hour, double-blind study to assess the safety, tolerability, and fat absorption using RELiZORB in patients with Exocrine Pancreatic Insufficiency (EPI) due to Cystic Fibrosis



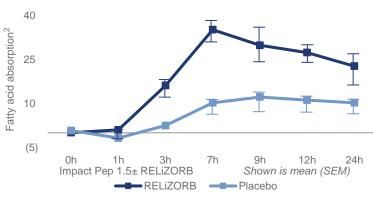
2.8-fold overall increase in total plasma concentrations of **omega fatty acids** vs. placebo



57% reduction in the incidence of diarrhea



Digestive cartridge use was safe and well tolerated



Sustained fat absorption

The ASSURE Study³

The ASSURE study is a 90-day open-label study focused on fatty acid absorption with overnight use of RELiZORB



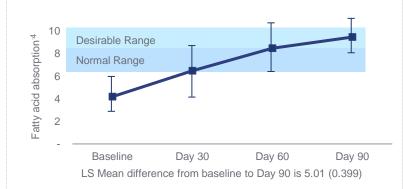
61% of participants demonstrated improvement in weight percentiles



0% reported incidence of diarrhea at day 90



Digestive cartridge use was generally safe and well tolerated and avoiding GI symptoms (e.g. diarrhea, which are key pain points for patients)



Demonstrated increase in BMI⁶

The BRIDGE Study⁵

The BRIDGE study is a 12-month open-label study during which RELiZORB was used with overnight EN to study change in height, body weight, and BMI6 in patients with Cystic Fibrosis



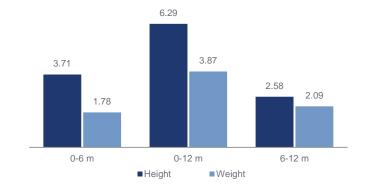
50%+ of patients achieved >50th percentile BMI vs. 37% at baseline



Statistically significant improvements in height and weight



Safe and well tolerated with no significant adverse events



- Freedman S. et al. J Pediatr Gastroenterol Nutr. 2017:65(1):97-101
- Change from baseline in omega fatty acids (docosahexaenoic acid and eicosapentaenoic acid) (pg / mL)
- Stevens J. et al. J Pediatr Gastroenterol Nutr. 2018:67(4):527-532
- % increase in red blood cell omega fatty acids (docosahexaenoic acid and
- Sathe M. et al. J Pediatr Gastroenterol Nutr. 2021;27(1):18-23

1 in 3 Cystic Fibrosis patients on Enteral Nutrition in the US currently use RELiZORB, with penetration expected to significantly increase



Significant unmet need for Cystic Fibrosis patients on EN

RELIZORB provides significant quality-of-life improvements



Successful payer access achieved



General malnutrition, weight loss and stunted growth caused by malabsorption



Range of life-limiting GI symptoms from overnight enteral feeds, especially during the first weeks of EN



Patients on EN need to take PERTs1 during their feeds, which includes waking up in the middle of the night

Weight gain and improved growth from improved absorption

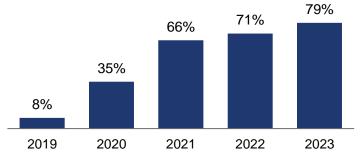
Reduction in GI events from improved absorption

Increased energy levels from improved sleep (uninterrupted nights) and absorption

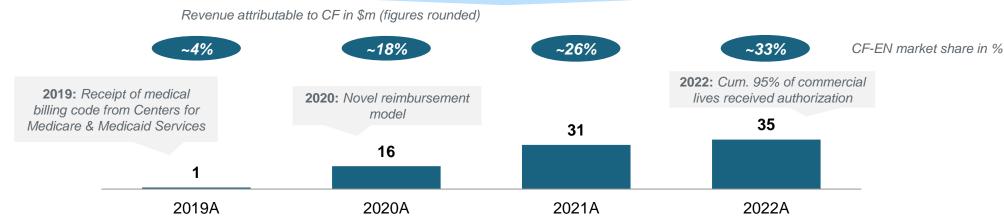
79% of commercial lives covered by published Medical Policy²

States with successful Medicaid claims achieved

% of commercial lives covered by published Medical Policy



Compelling value proposition for patients and clinicians has led to broad penetration



Pancreatic Enzyme Replacement Therapy are oral capsules or tablets that provide the patient pancreatic enzymes to aid with absorption after meals

95% of Commercial lives have received authorization

Next-generation device ALC-078 enables expanded use in Short Bowel Syndrome with an addressable US market of ~\$1.4bn



Next-gen device (ALC-078) features innovative engineering modifications



Tangible design improvements expand versatility



Compatible with bolus and continuous feeding enabling greater flexibility



Cartridge limit per patient increased from 2 to 6 per day



SBS formula compatibility of ~78%¹ due to to increased flowability

Unlocks access to patients across CF, SBS, and other disease states

New device broadens versatility across CF and SBS

- ALC-078 expands use across disease states by increasing utility for bolus feeding, which is used by both CF and SBS patients
- SBS patients in particular benefit from increased daily cartridge limits, as a single cartridge can hydrolyze fats in 500ml of enteral formula
- SBS patients tend to receive about ~80% of their calories from EN (often >1L of formula per day)

Strong initial results from pre-clinical data

- Physicians reacted positively to absorption and parenteral nutrition/ enteral nutrition caloric intake seen in the pig study efficacy data
- Among pediatric GIs familiar with RELiZORB, there was high confidence in safety profile of ALC-078 after review the pig study safety data

Leverage RELiZORB's recognition among prescribers

- Current RELiZORB viewed favorably among pediatric gastroenterologists
- Utilize this positive halo effect for ALC-078, which will likely support accelerated uptake in the pediatric SBS population

Alcresta is on track to obtain FDA 510(k) clearance for ALC-078 in 2024 (targeted)



ALC-078's 510(k) clearance is low-risk with RELiZORB as the Predicate device

Overview of 510(k) submission and clearance process

- 510(k) process is the pathway for FDA clearance of medical devices which are "substantially equivalent" to a device that has already been cleared by the FDA
- FDA's review of the submission will focus on comparing it to the previously cleared device, and determining whether the device is "substantially equivalent" in terms of intended use, technology, safety and effectiveness,
- 510(k) process is different from the drug approval process for pharmaceutical products; the drug approval process involves more extensive clinical testing and evaluation of safety and effectiveness, and typically takes longer than the 510(k) process for medical devices

Alcresta's regulatory strategy addresses key requirements for the 510(k) submission

Predicate device

- Alcresta plans to use the most recent and existing 510(k) clearance (obtained in 2019) for RELiZORB as a
 predicate device to demonstrate substantial equivalence for ALC-078
- Alcresta can leverage the existing regulatory pathway and data already established by the FDA, potentially streamlining the review process for ALC-078

Device classification

- · RELiZORB is classified as a Class II medical device
- Class II medical devices are considered to be of relatively moderate risk compared to Class III medical devices given they have existing precedent devices already cleared by the FDA

Device testing

 In addition to SBS animal studies, Alcresta has conducted the appropriate testing and evaluation to demonstrate that the device is safe and effective for its intended use with the testing performed in accordance with relevant standards and guidelines

Regulatory timeline



RELiZORB's broad label provides multiple upside opportunities across additional disease states with a US total addressable market of ~\$3.0bn



Published data, clinician familiarity and product innovation will drive penetration into these markets









Total Addressable Market

~\$300m

~30,000 patients

~\$300m

~30,000 patients

~\$2.0bn

~680,000 patients

~\$400m

~10,000 patients

Addressability

- Inpatients with acute pancreatitis with a high level of EN use
- Outpatients that have developed chronic pancreatitis after they leave the hospital have strong addressability for RELiZORB given high prevalence of EPI

- Patients with gastrointestinal cancers on EN are key addressable segments for the in-and outpatient TAMs given high prevalence of EPI
- Outpatient TAM is driven by long durations on EN and significant calorie requirements

- Ventilated ICU inpatients with EN intolerance are the addressable target population for RELiZORB
- EN intolerance frequently shows through decreased gastrointestinal tract function

- Pre-term infants with extrauterine growth failure on pre-term formula use EN and form the addressable population for RELiZORB
- Opportunity to expand to all very low birth weight infants on formula









Needed to capture market opportunity

2023E sales

Increased commercial resources

Increased commercial resources

Increased commercial resources

Device design updates

Turn-key and scalable rare disease platform with highly efficient operations and specialized capabilities

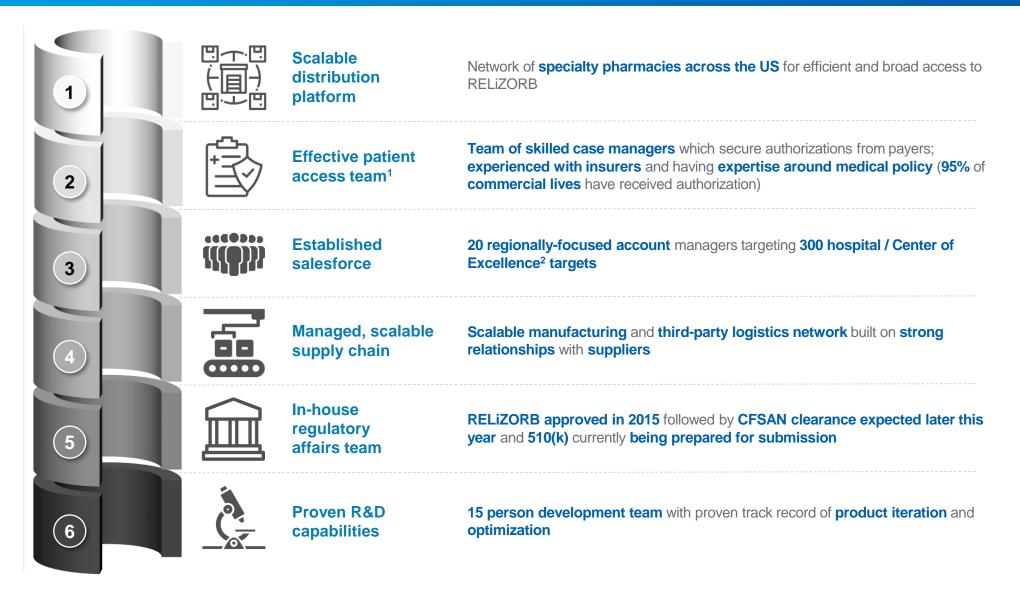




All key operational capabilities in place



Highly scalable with the ability to integrate additional rare disease products into existing infrastructure



Notes:

- Outsourced to a third-party service provider
- 2. Specialized hospital facility that offer comprehensive care, multidisciplinary collaboration, and contribution to research and innovation for a specific disease state or set of disease states

Modular manufacturing platform with robust 3rd party supplier network well-placed to continue expanding production of specialized product



Market leading expertise in bead formulation and enzyme immobilization

Unique

technologies

IMMOBEADS Macroporous polymer beads for immobilizing enzymes Protected by trade secrets



RELiZORB's technology has been optimized over the journey



Proprietary polymer chemistry with demonstrated safety profile, optimized for lipase immobilization



Developed high efficiency commercial scale immobilization methodology that optimized enzyme binding capacity and performance



Completed extensive analytical method development to ensure the highest safety, quality, and performance of Immobeads and iLipase



Defined formula residence time requirements for iLipase and RELiZORB device testing ensuring enhanced fat hydrolysis

Manufacturing processes have been designed to manage complexity and future scale requirements



Dedicated manufacturing facilities and production equipment were constructed, commissioned and qualified per ISO standards



Modular production designs were prioritized throughout the R&D phase to support future commercial scale-up capability



Extensive quality control protocols were implemented per required QMS and QTA to ensure all products meet strict quality standards

Secured and scalable supply chain



Long term supplier contracts protect trade secrets and contain exclusivity and non-compete clauses



Dedicated manufacturing suites, with modular design to support current and future capacity



Secure inventory with 2-year product shelf life (3-year shelf life expected for ALC-078)



Demonstrated high throughput manufacturing capabilities with excellent product quality and exemplary level of customer satisfaction



Supply chain has the capacity to deliver the required volumes to support the business plan

Efficient commercial platform with a proven reimbursement model delivers strong patient access and reimbursement success rate



Salesforce

RELiZORB Support Services¹









/

- Case management / reimbursement
- 20 Account Managers with strong nutrition experience placed strategically across the USA
- Key call point is dietitians who advocate to ultimate prescribers (Gastroenterologists, Pulmonologists, Oncologists)
- Organize events, regional speaker programs and establish partnerships with advocacy groups (e.g. ASPEN, the Cystic Fibrosis Foundation), and top-tier hospitals (e.g. Cleveland Clinic, Duke University)
- Supported by a robust brand plan and marketing tools to educate KOLs on RELiZORB's clinical outcomes, quality-of-life improvements, and safety profile

- Case managers liaise with payors to secure preauthorization from insurance for patients to whom HCPs have prescribed RELiZORB
- In the event of an initial application denial, case managers oversee the resubmission process and educated payers where necessary to get approval
- Revenue cycle management (RCM) team works closely with case managers to ensure proper reimbursement for RELiZORB, either via established contacts with payers or single-case agreements
- Staff with an average of 25 years of experience in patient services and clinical expertise in nursing, occupational therapy and nutrition all specializing in medically fragile populations

- Specialists identify payors who do not offer preauthorization for RELiZORB and have on multiple occasions approved RELiZORB following an initial denial
- Engage with the payors to consider revising their medical policy to cover RELiZORB and educate payers on why it is in their interest to include RELiZORB as part of policy
- Reiterate pain points for patients on EN suffering from fat malabsorption and the improved clinical outcomes and quality of life improvements



4% → **33%**

Market penetration into target CF patient population from 2019 to 2022



-**70**%²

of denials have been successfully reprocessed by the reimbursement team



79%

of commercial lives covered by published medical policy

Note:

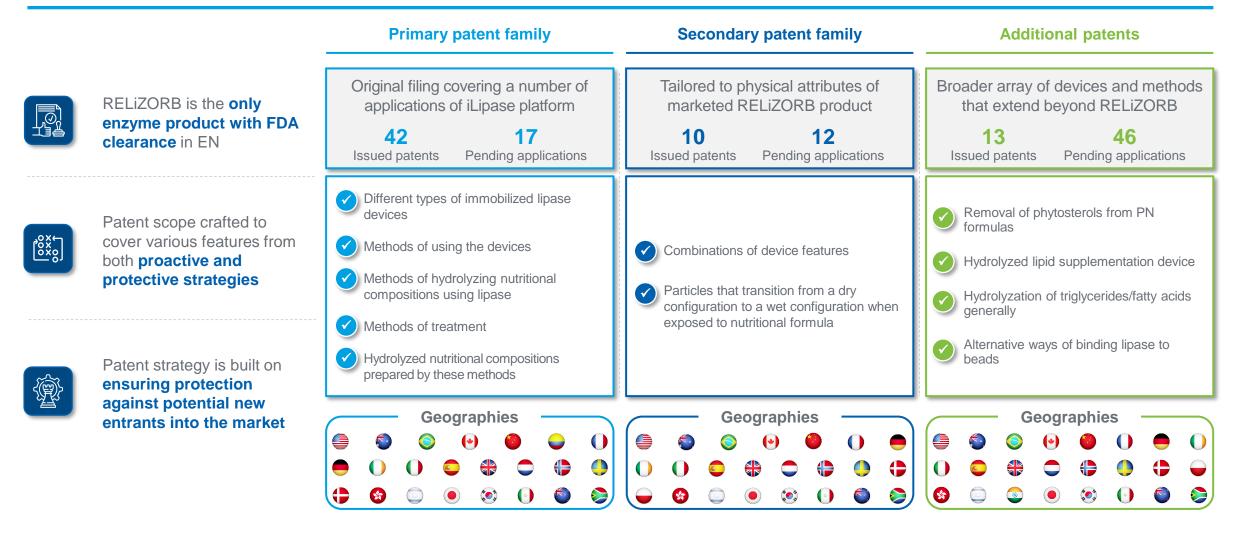
. Outsourced to a third-party service provider

2. Appeals persistence represents the proportion of patients prescribed RELiZORB that ultimately get access via appeals

Broad IP portfolio protects the method of breaking down fats outside the body, in addition to the RELiZORB / ALC-078 device itself



Device, method-of-use, and method-of-treatment patents provide broad protection out to 2036



High-performing leadership team has transformed Alcresta into a lean business with an engaged and motivated workforce



Experienced management team...



Daniel Orlando Chief Executive Officer 18+ years of experience





Abbott

...with a proven track record

During their tenure at Vericel, Alcresta management team refined the commercialization model which has delivered success at Alcresta

Mission-oriented culture

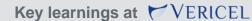
Dedicated employees deliver results for patients whose average age is 12



Jason Weiner Chief Commercial Officer 17+ years of experience



CRA





Commercialization of products reimbursed via medical benefit



Bill Scheinler Chief Legal Officer 23+ years of experience







Perfecting the reimbursement model with use of high-touch case managers

Effective medical policy communications to



Chris Parrish Chief Operations Officer 25+ years of experience







Aligning incentives with specialty pharmacies to ensure reliable dispensing

engage payers and adopt policies



Dave Recker MD Acting Chief Medical Officer 30+ years of experience





Pricing and coding launch strategy



98%

of employees say the vision and goals of Alcresta are important to them personally

Selected quotes



"When started using RELiZORB... I started feeling better, feeling stronger. I had more energy"

- Trenton, 17-year old student and lacrosse player living with Cystic Fibrosis



"I wake up in the morning and not feel full or bloated"

- Mariah, 21-year old living with Cystic Fibrosis who began losing weight at 19

High-growth rare disease GI platform with full commercial and operational capabilities delivering a ~30% EBITDA margin in 2023E



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