UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____ TO _____**

Commission File Number 001-39362

Gelesis Holdings, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**84-4730610**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
501 Boylston Street, Suite 6102 Boston, Massachusetts	**02116**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 456-4718

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, par value $0.0001 per share	GLS	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ 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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2022, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of common stock outstanding held by non-affiliates of the Registrant was approximately $84,333,000, based on the closing price of the shares of common stock on the New York Stock Exchange on June 30, 2022 of $1.55.

The number of shares of Registrant's Common Stock outstanding as of March 24,2023 was 73,332,588.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Auditor Firm Id: 185 Auditor Name: KPMG LLP Auditor Location: Boston, MA

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ended December 31, 2022 (the "Form 10-K", including, without limitation, statements under the headings "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes," "estimates," "anticipates," "expects," "intends," "plans," "may," "will," "potential," "projects," "predicts," "continue," or "should," or, in each case, their negative or other variations or comparable terminology. There can be no assurance that actual results will not materially differ from expectations. Such statements include, but are not limited to, any statements relating to our financial and business performance, implementation, market acceptance and success of our business model, our ability to expand the scope of our offerings, and our ability to comply with the extensive, complex and evolving regulatory requirements applicable to the healthcare industry. These statements are based on management's current expectations, but actual results may differ materially due to various factors.

The forward-looking statements contained in this Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. Future developments affecting us may not be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) and other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under Item 1A: "Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. These risks and others described under Item 1A: "Risk Factors" may not be exhaustive.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and developments in the industry in which we operate may differ materially from those made in or suggested by the forward-looking statements contained in this Form 10-K. In addition, even if our results of operations, financial condition and liquidity, and developments in the industry in which we operate are consistent with the forward-looking statements contained in this Form 10-K, those results or developments may not be indicative of results or developments in subsequent periods.

BASIS OF PRESENTATION

On January 13, 2022 (the "Closing Date"), Capstar Special Purpose Acquisition Corp., a Delaware corporation and our predecessor company ("CPSR"), consummated the previously announced business combination (the "Business Combination"), pursuant to the terms of the Business Combination Agreement, dated as of July 19, 2021 (as amended on November 8, 2021 and December 30, 2021, the "Business Combination Agreement"), by and among CPSR, CPSR Gelesis Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of CPSR ("Merger Sub"), and Gelesis, Inc., a Delaware corporation (together with its consolidated subsidiaries, "Legacy Gelesis").

Pursuant to the Business Combination Agreement, on the Closing Date, (i) Merger Sub merged with and into Legacy Gelesis (the "Merger"), with Legacy Gelesis as the surviving company in the Merger, and, after giving effect to such Merger, Legacy Gelesis became a wholly-owned subsidiary of CPSR and (ii) CPSR changed its name to "Gelesis Holdings, Inc." (together with its consolidated subsidiaries, "New Gelesis" or the "Company").

In accordance with the terms and subject to the conditions of the Business Combination Agreement, at the effective time of the Merger (the "Effective Time"), based on an implied Legacy Gelesis equity value of $675 million, (i) each share of Legacy Gelesis common stock outstanding as of immediately prior to the Effective Time was exchanged for shares of the common stock, par value $0.0001 per share, of New Gelesis ("Common Stock"); (ii) all vested and unvested options of Legacy Gelesis were assumed by New Gelesis, to be settled or exercisable for shares of Common Stock; (iii) each outstanding warrant of Legacy Gelesis was assumed by New Gelesis and became a warrant to purchase shares of Common Stock; (iv) each share of Class A common stock, par value $0.0001 per share, of CPSR ("CPSR Class A Common Stock") and each share of Class B common stock, par value $0.0001 per share, of CPSR ("CPSR Class B Common Stock") that was issued and outstanding immediately prior to the Effective Time became one share of Common Stock following the consummation of the Business Combination; (v) each outstanding redeemable public warrant of CPSR was automatically converted into a redeemable public warrant to purchase a share of Common Stock; and (vi) each outstanding private placement warrant of CPSR was automatically converted into a private placement warrant to purchase a share of Common Stock.

In this Form 10-K, Gelesis Holdings, Inc. (together with its subsidiaries) is referred to as "Gelesis", the "Company," "we," "us," or "our."

PART I

Item 1. Business.

Overview

Gelesis is a commercial stage biotherapeutics company built for consumer engagement. We are focused on advancing first-in-class superabsorbent hydrogel therapeutics for chronic gastrointestinal, or GI, diseases including excess weight, type 2 diabetes, non-alcoholic fatty liver disease/non-alcoholic steatohepatitis ("NAFLD/NASH"), functional constipation ("FC"), and inflammatory bowel disease. Our biomimetic superabsorbent hydrogels are inspired by the composition and mechanical properties (e.g. firmness) of raw vegetables. They are conveniently administered in capsules taken with water to create a much larger volume of small, non-aggregating hydrogel pieces that become an integrated part of the meals, and act locally in the digestive system.

Our first product, Plenity, and our other product candidates are based on a proprietary hydrogel technology that works mechanically, as opposed to via a chemical mode of action, and exclusively in the gastrointestinal, or GI, tract rather than systemically or through surgical intervention. Plenity is indicated for over 150 million Americans, the largest number of adults struggling with excess weight (i.e., a body mass index (kg/m2), or BMI, of 25 – 40) of any prescription oral weight-management aid and the only one indicated for the entire range of overweight population, including those without co-morbidities such as diabetes and cardiovascular diseases. Plenity is marketed directly to potential members, who access it through telehealth and traditional healthcare provider services. We refer to those who are prescribed Plenity as our members — not customers — because we view our relationship with them as a long-term journey of support, not as a transactional relationship. This consumer-directed model is uniquely enabled by Plenity's strong safety and tolerability profile. Our business is built on a subscription model, as monthly Plenity kits are delivered to our members' homes. We leverage the latest technologies with telehealth, mail-order distribution, consumer engagement, and our native digital technology platform. Plenity is an orally administered capsule that employs multiple mechanisms of action along the GI tract to aid in weight management by creating small firm 3D structures, similar to ingested raw vegetables, which create a sensation of feeling fuller. Using a biomimetic approach, we developed the first-of-its-kind superabsorbent hydrogel technology, inspired by the composition (e.g., water and cellulose) and mechanical properties (e.g. elasticity or firmness) of ingested raw vegetables. We designed Plenity and our other hydrogels to address several critical challenges of the modern diet: portion size, caloric density, and food composition. For optimal safety and efficacy, these hydrogel particles are engineered to rapidly absorb and release water at specific locations in the GI tract. Plenity does not act systemically and is not absorbed by the body. Instead, it acts locally in the GI tract by changing the volume, firmness, and reducing the caloric density of ingested meals. Because it acts mechanically and it is the first of its kind, Plenity is regulated as a novel medical device and was granted *de novo* authorization. In January 2023, we submitted a premarket notification, or 510(k), to the FDA to change Plenity from prescription-only to over-the-counter, or OTC, in the United States and anticipate the

FDA's decision on our 510(k) submission by the third quarter of 2023. Our product pipeline also includes multiple other potential therapeutic candidates for common chronic conditions affected by gut health that are currently in clinical and preclinical testing, including type 2 diabetes, NAFLD, NASH, and FC, all based on our hydrogel technology.

Obesity and obesity-related metabolic diseases represent a global health challenge for which there are few safe and effective interventions. These conditions are associated with comorbidities such as type 2 diabetes, hypertension, and heart disease.

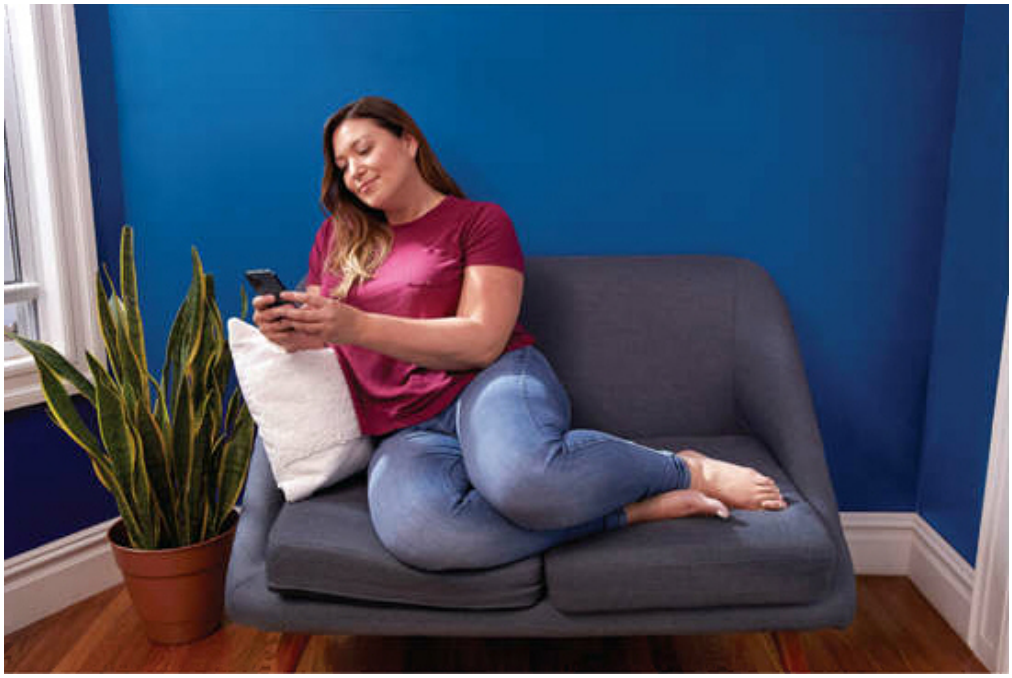
There are limited available treatments that address the overweight and obesity epidemic safely and effectively. Available therapies include pharmaceuticals and surgical interventions, including device implantation. These approaches are associated with safety concerns that limit their use. Conversely, we believe our hydrogel technology presents a breakthrough in material science as it is the first and only superabsorbent hydrogel that is constructed from building blocks used in foods and specifically engineered to achieve its medical purpose. Our first commercial product based on this technology, Plenity, is clinically validated and was granted *de novo* classification by the FDA to aid in weight management in adults with overweight or obesity, when used in conjunction with diet and exercise. The types of FDA marketing authorization available to a medical device are premarket notification (also called 510(k) when a predicate device exists) and premarket approval (also called PMA) for higher risk Class III devices. *De novo* classification is a pathway to market for low to medium risk novel devices for which there is no predicate.

Plenity's *de novo* authorization included clinical trials and other data that demonstrated assurance of safety and effectiveness. Plenity has the broadest label of any FDA-regulated weight management approach as it is indicated for the largest number of adults struggling with excess weight, offering a safe, convenient and effective oral treatment option.

Our biomimetic hydrogel, which is engineered to rapidly absorb and release water at specific locations in the GI tract, is synthesized through a multi-step, proprietary process using a specific form of modified cellulose and citric acid, both of which are generally recognized as safe, or GRAS, by the Food and Drug Administration, or FDA, and are commonly used in the food industry. In our manufacturing process, we crosslink the modified cellulose with citric acid to form a three-dimensional matrix, resulting in the desired properties of Plenity. Each Plenity capsule contains thousands of hydrogel particles, with each particle approximately the size of a grain of salt. We designed the Plenity capsule to be ingested with water before a meal. In the stomach, the hydrogel particles are released from the capsules and rapidly absorb water, hydrating to approximately 100 times their original size. When fully hydrated, each gel particle is, on average, approximately 2 mm in diameter and its elastic response (a measurement of the ability of matter to recover its original shape after deformation) is similar to that of ingested raw vegetables. The hydrogel particles mix homogeneously with food and travel through the GI tract and are designed to induce satiety and improve glycemic control through multiple mechanisms of action. Once in the large intestine, the particles partially degrade and release most of the water, which is reabsorbed by the body. The remaining degraded particles are then eliminated by the body in the same manner as raw vegetables.

Our Commercial Approach

Our first product, Plenity, is a prescription therapy delivered through a direct-to-consumer approach. It is the first weight management product to provide consumer access through a telehealth platform as well as through traditional healthcare provider services at launch. Our direct-to-consumer commercial approach integrates proven traditional and online consumer marketing strategies with our synergistic partnerships in telehealth and online pharmacy industries.



By allowing consumers to seek out our product on their own time, on their own terms, and from the privacy of their homes, we aim to drive consumer demand. Through our telehealth model in partnership with leading telehealth provider Ro, consumers can initiate an evaluation with a board certified, independent physician online at any time that is convenient to them. We anticipate that some consumers will want to see their own physician to discuss Plenity. We are undertaking a physician and healthcare provider education program to drive professional awareness of Plenity.

Plenity is affordably and transparently priced at $98 for a 28-day supply ($1.75/meal). Knowing the product cost when it is prescribed by a healthcare provider, not having to deal with the hurdles and hassle of payor, co-pays or reimbursement hoops further lowers the barrier to access. We have priced Plenity at an amount we believe will allow a large portion of the 150 million target population to afford to pay for the product out of pocket. We anticipate our commercial approach will also remove the significant and ever-growing margin erosion forced on healthcare companies from payors and pharmaceutical benefit managers in order to gain access to their controlled patient pools. Our business model is driven by consumer demand with out-of-pocket consumer payment and is not dependent on reimbursement from third-party payors, such as government health programs and private insurance companies.

Obesity is a chronic medical condition and we believe people require ongoing, often long-term, support to achieve and maintain weight loss. Given its safety profile and broad FDA label, Plenity can be taken without limitation to duration of therapy — addressing this long-term challenge. We view our relationship with our members as long term and anticipate that some people will take Plenity chronically, and some will stop or pause treatment. Based on the data we have collected, 70% of consumers responded that they would try Plenity again.

Pricing & Availability

Plenity is available by prescription via a telehealth consultation with a physician trained in weight management support, with free, unlimited follow-up visits as needed. Consumers may visit myplenity.com to start their online consultations or speak with their physician to determine if the Plenity prescription therapy is their best treatment option. A Plenity subscription costs $98 for a four-week supply ($1.75 per meal). Members may pause their subscription or delay shipment at any time.

Manufacturing

Manufacturing the superabsorbent hydrogel used in Plenity and our other product candidates is a unique, proprietary process that is performed in-house by our subsidiary, Gelesis S.r.l., located in Italy. During 2020, we completed a limited manufacturing scale-up to enable the beta launch of Plenity in the U.S. market, while simultaneously constructing state-of-the-art commercial-scale facilities to enable the full launch of Plenity. Production at our first commercial-scale manufacturing facility commenced in the fourth quarter of 2021, with the facility designed to accommodate three commercial-scale manufacturing lines, which is equivalent to an aggregate manufacturing capacity of approximately 480,000 Plenity 28-day supply units produced on a monthly basis when development is complete.

In addition to our existing know-how in manufacturing superabsorbent hydrogels, we continue to seek improvements in manufacturing efficiency through research and development in material science and commercial-scale real-world optimization. To date, we have invested over $50 million in commercial manufacturing capabilities. We are currently capable of producing up to 80,000 Plenity 28-day supply units on a monthly basis, and we expect we will be able to produce up to 160,000 Plenity 28-day supply units on a monthly basis by the second quarter of 2023, with capability to scale-up to 320,000 Plenity 28-day supply units on a monthly basis by the fourth quarter of 2023, and reaching full capacity of 480,000 Plenity 28-day supply units on a monthly basis by the end of 2024. We also own land to build a second commercial-scale manufacturing facility. Our second commercial-scale facility is designed to accommodate six commercial-scale manufacturing lines, which is equivalent to an aggregate manufacturing capacity of approximately 960,000 Plenity 28-day supply units produced on a monthly basis when development is complete. Future development of our manufacturing facilities, including planned increases in capacity, is contingent on the timing and magnitude of additional fundraising as well the demand for and sales of Plenity.

We engage contract-manufacturing organizations in North America to perform ancillary finished-good packaging services as a means of controlling costs and enabling growth capabilities.

Our Competitive Strengths

- **Unmet Need**. In the United States, roughly 7 out of 10 Americans struggle with their weight. Our first product, Plenity, is indicated for the largest number of adults struggling with their weight (approximately 150 million Americans) as compared to any other weight management prescription product and has no limitation on duration of therapy. Seventy percent (70%) of our members have never tried a prescription weight management product before, indicating Plenity is bringing new people into the category of prescription weight management products.
- **Attractive Efficacy and Safety Profile**. In clinical trials, six out of ten people achieved clinically meaningful weight loss in six months on Plenity, averaging a loss 10% of their total body weight (or an average of 22 pounds), with a side effect profile similar to placebo, and no serious adverse events.

The strong safety, efficacy, and tolerability profile of Plenity provides a clinically validated option as a first line of defense after diet and exercise for people who are just overweight, before the onset of obesity, many of whom did not have any prescription option before.

- **Consumer Focus and Engagement**. We leverage telehealth and traditional healthcare to provide members with easy access to Plenity. We have developed the infrastructure to directly engage with our members in a digital ecosystem designed to also provide behavioral and educational support for our members' weight loss journey. Through our platform we provide our members with immediate access to physicians with real-time communications through telehealth. We believe this consumer-focused approach empowers our members to improve and change their diet, lifestyle and health. We offer our members transparent pricing and home delivery with two-day pharmacy direct shipping. Our reliance on direct-to-consumer marketing as our primary demand driver should allow us to improve the efficiency of our sales force investments. The consumer pull created reduces the need for typical high healthcare provider, or HCP, call frequencies and allows for efficient use of a limited sales force.
- **Proven Early Success**. Our broad launch successfully demonstrated that the product profile resonates with users, and we believe that it indicates strong future demand for Plenity given a broad label in the underserved weight loss market. As weight management is a chronic medical condition, we see the potential for long-lived, recurring revenues if consumers make Plenity a part of their everyday weight management routine.
- **Global Scalability**. Worldwide, more than 1.9 billion adults aged 18 years and older have unhealthy weight and of these over 650 million adults are classified as having obesity. We believe our commercial infrastructure is purpose-built to scale quickly and efficiently to accommodate new geographies. We have partnered with China Medical System Holdings Limited for commercialization of Plenity in Greater China (including Mainland China, Hong Kong, Macau,

and Taiwan), Singapore and United Arab Emirates. With our CE Mark authorization for Plenity in Europe, we intend to pursue expansion through strategic partnerships or direct commercialization.

- **Profit Margin Potential**. We believe that our proprietary manufacturing process and agile distribution and supply chain networks will provide sustainable profit margins.
- **New Product Pipeline**. We believe that our superabsorbent hydrogel technology can address large patient populations with chronic conditions related to obesity and have a pipeline of product candidates which we expect to advance through the FDA's *de novo* classification or 510(k) pathways as clinical data become available. We are developing manufacturing capacity for our hydrogels using a novel, proprietary process which we perform at our own facilities. We have nine families of patents and more than 130 individual patents and patent applications directed to compositions of matter and methods of production for Plenity, other product candidates and our hydrogel technology as well as methods of use for certain hydrogels.
- **Management Team**. We are a founder-led team that combines innovative scientific thinkers and proven industry leaders in research and discovery, clinical development and product approval, and consumer driven commercialization.

Market Overview

Global Epidemic: Overweight and Obesity

Obesity is a serious medical condition that is growing rapidly in prevalence worldwide. It has been designated by the American Medical Association, or AMA, as a "multi-metabolic and hormonal disease state." Between 1988 and 1994, 23% of adults in the United States 20 years of age and older, or approximately 40 million, had obesity according to a CDC report. However, between 2017-2018, this number had risen to 42.5% or approximately 105 million, representing a 263% increase. Furthermore, the CDC reported that an additional 31% of adults in the United States 20 years of age and older, or approximately 75 million, were overweight, with many of these individuals expected to cross the threshold into obesity in the near future. Globally, there were more than 1.9 billion adults 18 years of age and older that had an unhealthy weight, of which approximately 650 million in 2016 had obesity, according to the WHO.

In addition to the adult population, the pediatric population is also suffering from an obesity epidemic. According to the CDC, by 2016, obesity in the United States has more than tripled in children and adolescents since the 1970s. In 2017-2018, more than one-third of children and adolescents had excess weight or obesity. According to a study by WHO, in 2016 over 340 million children and adolescents aged 5-19 had excess weight or obesity.

The designations "overweight" and "having obesity" are based on the thresholds of BMI, which measures weight on a height-adjusted basis. A person with a BMI of 30 or greater is typically classified as having obesity, while a person with a BMI of between 25 and 30 is typically classified as overweight. BMI is considered the standard within the medical community for measuring body fat and is recommended by the National Institutes of Health, or NIH, as a guide for the classification of people with excess weight and obesity.

There are a number of comorbidities caused by having either overweight or obesity. In the United States, obesity-related medical care costs were an estimated $147 billion in 2008 dollars. Approximately 300,000 people in the United States die each year as a result of obesity and its associated comorbidities, according to the Department of Health and Human Services, or HHS. According to the WHO, 44% of diabetes diagnoses, 23% of ischemic heart disease diagnoses, and a significant percentage of certain cancer diagnoses can be attributed to being either having overweight or obesity.

The Covid-19 pandemic has placed even greater focus on the need to urgently address obesity. Unfortunately, Covid-19-related lockdowns appear to have exacerbated the problem, as an estimated 71 million Americans gained weight during the pandemic. Further, the World Obesity Federation (WOF) reported that 2.2 million of the 2.5 million (or 90%) of global Covid-19 deaths were in countries with high levels of obesity. In fact, people with obesity are 48% more likely to die of Covid-19.

Barriers to Weight Management

Despite over 70% of adults in the United States having a BMI greater than 25, with a higher risk for serious medical complications, only 2% of this population are prescribed drug therapy. In contrast, more than 80% of patients with type 2 diabetes are prescribed anti-diabetes pharmacotherapy. Considering that obesity is a major cause of type 2 diabetes, we believe these realities are paradoxical. Multiple studies have indicated that therapeutic inertia is high in the management of weight, particularly in patients with lower BMI. The highest rates of weight management interventions by primary care physicians occur for patients with BMI larger than 40 and the lowest for patients in the overweight category. A 2019 study of several large healthcare organizations reported that patients with a BMI greater than 35 accounted for 50.3% of all prescriptions for weight management pharmacotherapy, despite only making up

25.3% of the total patient sample. This study also found that the median BMI of a patient receiving weight management pharmacotherapy was 37.2. These results suggest that prescribers restrict the use of drug therapy to only patients in whom the benefit justifies the risk.

Other barriers to weight management include shorter health care provider visits allowing for limited time to educate patients on injection techniques (required of some pharmacotherapy options), titration of medication dose, signs and symptoms to monitor to prevent serious adverse events, how to manage milder drug-related symptoms such as nausea, etc.

In addition, we believe much of the inertia in addressing weight management can be attributed to the prevailing societal bias that obesity is a matter of personal responsibility and the false belief that "eat less and move more" will work for most people. A large number of people will not achieve meaningful and/or long-lasting weight loss simply by dieting and exercising on their own. Without help from drug, device or surgery, many people will fail. Finally, cost is a significant barrier for the majority of the population. Few weight management options are covered by third party payors and these drugs or interventions can be very costly and remain unaffordable.

Limitations of Current Treatments

Current treatments for patients with excess weight or obesity include lifestyle interventions (dietary changes, behavioral modification, increased physical activities, etc.), pharmacotherapies, endoscopic applications of intragastric balloons, and bariatric surgery that creates permanent changes in the GI tract anatomy. Lifestyle interventions focused on diet, and exercise and behavioral modification are typically prescribed as an initial treatment for a patient with overweight or obesity. However, lifestyle interventions frequently fail to produce adequate and durable weight loss due to poor compliance and other limiting factors. In conjunction with lifestyle interventions, pharmacotherapies are approved for use by patients with a BMI of 27 or greater with at least one comorbidity, and all patients with a BMI of 30 or greater. Bariatric surgery, including gastric bypass and gastric banding procedures, is typically limited to patients with severe obesity, a BMI of greater than 40 or greater than 35 with at least one comorbidity. Although these procedures can produce dramatic weight loss results in this population, they come with a multitude of risks, including those inherent in surgery, such as an increased risk of death.

There are currently five pharmaceutical products approved in the United States for long-term weight management in people with excess weight and obesity, including products such as Orlistat, a combination product of phentermine and extended release topiramate, a combination product of naltrexone extended release and bupropion extended release; a higher dose subcutaneous injection of liraglutide, and a weekly subcutaneous injection of semaglutide. Each of these products act through mechanisms that require the product to be absorbed into the patient's blood stream. As a result, these products carry the risk of systemic side effects, such as adverse gastrointestinal, cardiovascular and central nervous system effects, some of which can be serious or even life-threatening. Each of these approvals has also been accompanied by requirements for post-marketing safety studies to assess the safety of long-term treatment, with an emphasis on potential adverse cardiovascular side effects. In addition, Qsymia has been designated a Schedule IV controlled substance due to their potential for abuse. Furthermore, in connection with its approval of Qsymia, the FDA required a Risk Evaluation and Mitigation Strategy, or REMS, program to inform prescribers and women with the potential to become pregnant about the increased risk of congenital malformation in infants exposed to Qsymia in early pregnancy, as well as limiting access to certified pharmacies. The label for Contrave includes a black box warning from the FDA to alert health care professionals and patients to the increased risk of suicidal thoughts and behaviors, as well as serious neuropsychiatric events, associated with bupropion. These drugs also compete against generic forms of phentermine, topiramate, naltrexone, and bupropion. None of these products have been approved for use in pediatric patients and phentermine is only approved for short term use of no longer than 12 weeks.

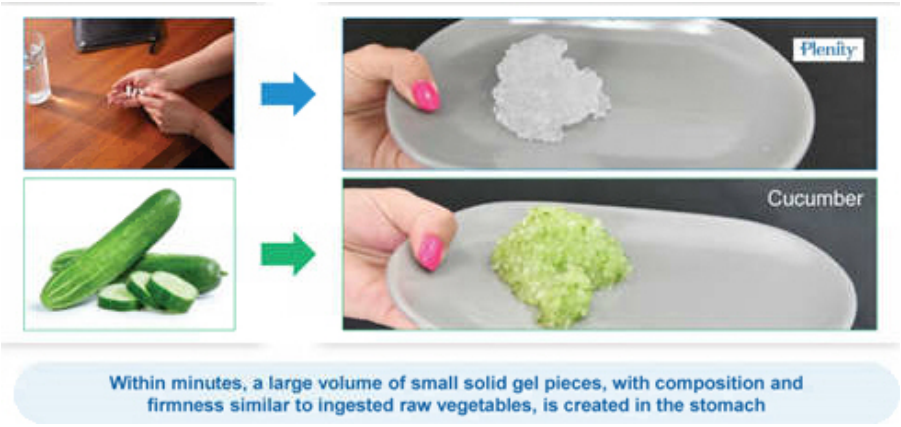
All current prescribed pharmacotherapies are indicated only for individuals with BMI $\geq$ 30 or individuals with BMI $\geq$ 27 with existing health conditions brought on by extra weight such as diabetes, blood pressure or heart disease. More invasive treatment options include intragastric balloons, which reduce gastric volume via a foreign object such as a balloon that, in most cases, is placed by an endoscopic procedure similar to a gastroscopy in the stomach. The balloon is left in place for 6-12 months and then removed via endoscopy.

Long-term data is limited and weight loss is not anticipated to be maintained once the balloon is removed. Endoscopic procedures needed for placement and removal, in addition to the potential associated complications, limit their adoption. As of April 2020, the FDA has received reports of a total of 18 deaths that occurred in patients with liquid-filled intragastric balloon systems worldwide. Eight of these 18 deaths were patients in the United States.

We believe there is an urgent demand for affordable therapies that result in clinically meaningful weight loss with little or no additional safety risk, opening the possibility to treat people earlier at a lower BMI and potentially prevent or delay the progression of complications related to weight gain.

Our Approach to Weight Management

Plenity — A Biomimetic Approach. There are many lifestyle related drivers that contributed to the dramatic increase in obesity in the developed world over the last 50 years. One major contributor is the significant increase in the portion size of meals and another major contributor is the quality and composition of food, which has shifted to calorie dense and heavily processed. In addition there is a significant reduction in the consumption of hypocaloric foods, especially foods rich with fiber like vegetables and fruits. One of the reasons vegetables and fruits are so important to a healthy diet — in addition to their nutritional value — is that they provide bulk and texture to a meal and maintain their shape, structure, and firmness, through nearly the entire digestive process. They are also known to have important effect on the gut health. That's why you tend to feel fuller when you eat a big salad with a meal, and thereby desire to eat less. We wanted to use science to create the same effect.



Plenity was designed using the principles of biomimicry. Biomimicry is the design of materials modeled on biologic structures — thereby leveraging natural designs that have evolved to work favorably in the body. Many modern inventions were developed by studying and mimicking the natural designs of plants and animals. Taking a biomimetic approach and therefore leveraging on "nature's R&D," Plenity is a first-of-its-kind superabsorbent hydrogel technology, specifically engineered to have the composition (i.e. large amount of water held by cellulose) and mechanical properties (i.e., elasticity or firmness) as ingested raw vegetables.

Our hydrogels are designed to address several critical challenges of the modern diet: portion size, caloric density, and food composition. Our solution to this challenge: the first super absorbent hydrogel technology based on naturally-derived building blocks, creating small firm 3D structures, similar to ingested raw vegetables, designed to create a sensation of feeling fuller. In the stomach the hydrogel particles form small solid non-aggregating gel pieces consisting of water held by 3D cellulose structures, similar to raw vegetables. There, they are homogeneously mixed with ingested foods, increasing volume and firmness while reducing the caloric density of meals. Like vegetables, the hydrogel pieces are not absorbed and ultimately partially degrade in the large intestine, releasing their water before leaving the body naturally. In clinical trials, 6 out of 10 people achieved clinically meaningful weight loss without serious side effects — losing an average of 10% of their total body weight or approximately 22 pounds.

The technology is non-invasive (taken by capsule, not an injectable), easy to use (the dosing is simple), and straightforward (with minimal clinical follow up). Plenity is non-systemic, not absorbed, and non-habit forming, giving consumers an option that is scientifically proven and clinically validated, FDA cleared, and rooted in nature.

The packaging for Plenity is designed for convenience and to be discrete: each pod contains one dose and is small enough to fit in your pocket. By having Plenity in pods it makes it easier to carry the dose needed for the day. Additionally, a week supply comes in a separate container of 14 pods so it makes it easy to travel with or keep at work for lunch and the rest at home.

Plenity is not a drug, so it does not negatively impact the brain as stimulants do, or affect other internal organs. It is non-systemic, and does not use hormones or require injections. It is also not habit forming and there is no limit on how long you can take Plenity.

We believe Plenity provides the following safety advantages over currently available therapies:

- acts mechanically in the GI tract and is not absorbed into the blood stream, avoiding acute and chronic side effects caused by systemically acting therapies;
- passes with food through the GI tract with no procedure required for introduction or removal;

- has a natural cycling effect similar to food, preventing the habituation, adaptation, and irritation of the GI tract associated with some therapies, such as gastric balloons; and
- is engineered using components that are considered GRAS by the FDA and widely used in the food industry.

Mechanisms of Action

Plenity is designed to act mechanically throughout the GI tract, working with the body's natural digestive process to occupy space in the stomach and small intestine without being absorbed as follows:

(1) Twenty minutes before lunch and dinner, three Plenity capsules are taken with two glasses (16 ounces) of water.

(2) The capsules are rapidly dissolved in the water, releasing thousands of individual hydrogel particles.

(3) These particles absorb up to 100X their size in water, forming small pieces of solid gel. They mix homogenously with the foods, increasing the volume and firmness of the ingested meals while reducing the caloric density, therefore promoting satiety and fullness.

(4) The hydrogel pieces are not digested and maintain their solid gel form as they pass throughout the small intestine as well. This prolongs the sensation of satiety and fullness.

(5) Upon transition into the large intestine, the digestive enzymes degrade the three-dimensional structure of the hydrogel particles resulting in the release of most of the water, which is then reabsorbed in the body. The remaining degraded particles pass through and are eliminated naturally from the body.

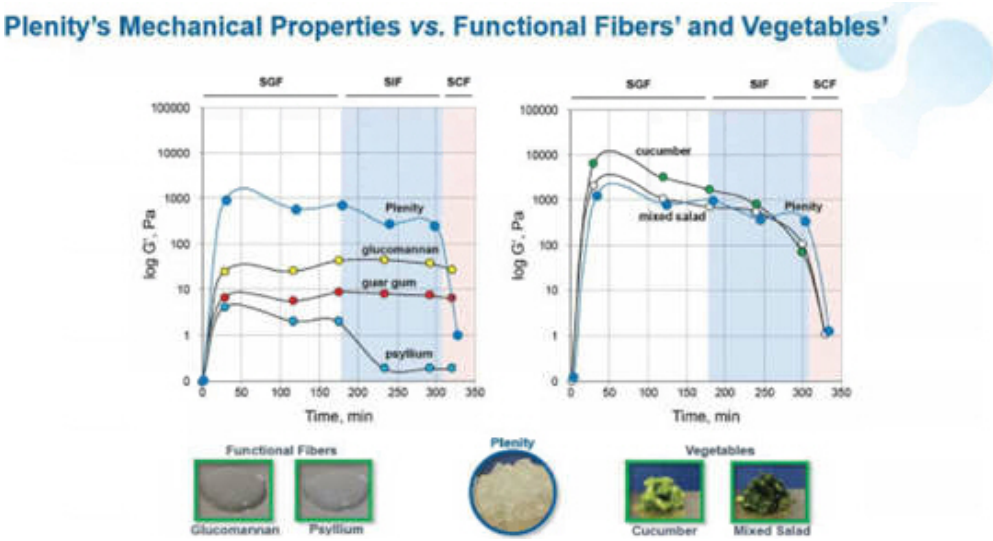
During this process, there are several relevant characteristics of Plenity that we believe ensure that the hydrogel travels safely through the body.

(1) "Caloric density" refers to the number of calories in a given mass of food.

How Plenity differs from fibers

Plenity forms a solid gel in the stomach and small intestine, which is orders of magnitude firmer than hydrated functional fibers like psyllium or glucomannan. This is because Plenity particles have a three-dimensional structure holding water inside them, while functional fibers have a liner structure and only attract water to their surface. Therefore, Plenity creates a firm solid gel pieces very

similar to ingested raw vegetables, while functional fibers create viscous liquids, more like a soup. This firmness can be measured and demonstrated through digestive simulations, by measuring the firmness/elasticity, measured as G prime, or G', utilizing a rheometer.



Note: Data presented as log-transformed G' values in pascals.
SGF = simulated gastric fluid; SIF = simulated intestinal fluid; SCF = simulated colonic fluid.
Demitri C, et al. Poster presented at American Diabetes Association 77th Scientific Sessions. San Diego, CA; June 9-13, 2017.

Plenity clinical study overview

We conducted a double-blind, placebo-controlled, multi-center trial (the most rigorous type of trial design) of 436 adults with excess weight or obesity, with or without type 2 diabetes, BMI 27-40, over the course of 24 weeks (six months). Plenity or placebo were given in conjunction with diet and exercise.

The GLOW study was designed to measure:

- Whether at least 35% of individuals receiving Plenity lost 5% or more of their body weight
- Whether individuals receiving Plenity lost more of their body weight than individuals receiving placebo with a super-superiority margin of 3%

Key highlights of the GLOW study include the following:

- Six out of ten of individuals receiving Plenity lost at least 5% of their body weight with an average loss of 10% of total body weight (about 22 pounds). These responders also lost an average of 3.5 inches off of their waist measurement.
- The percent weight loss in all individuals receiving Plenity was 6.4% compared to a 4.4% loss for individuals receiving placebo (p=0.0007)
- 27% were "super-responders" to Plenity. Their average weight loss was 14% (about 30 pounds)
- Plenity doubled the odds of achieving 5% or greater weight loss compared to placebo
- Plenity had an overall side effect profile similar to placebo, and no serious adverse events. The most common side effects were diarrhea, distended abdomen, infrequent bowel movements, and flatulence Data from this study was presented in the journal Obesity authored by leading obesity experts including Frank L. Greenway, MD of LSU's Pennington Biomedical Research Center, Louis J. Aronne, MD of Weill Cornell Medicine, Caroline Apovian, MD of the Boston University School of Medicine, and Lee M. Kaplan, MD PhD of Massachusetts General Hospital. The paper was named Editor's Choice.

We have also conducted a small clinical trial in patients that are overweight or obese that was an extension of our larger GLOW study. This extension clinical trial looked at patients who stayed on Plenity for an additional six months (for a total of 12 months). This study demonstrated that, on average, subjects maintained the weight loss they achieved during the first six months of treatment or lost an additional small amount of weight in months six through twelve.

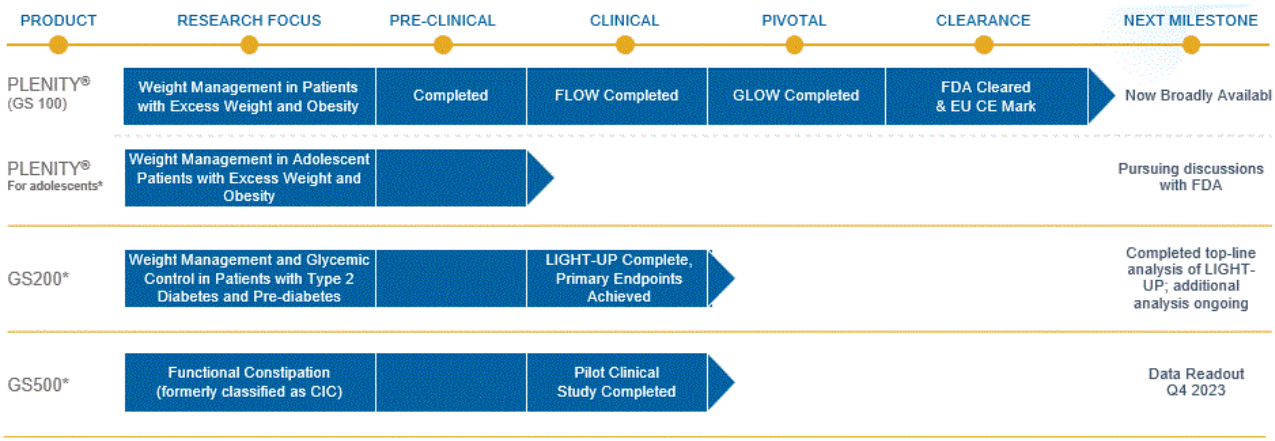
We believe that currently having limited long-term data does not impact the commercialization of Plenity for patients with a BMI of 25 to 40. This is because as part of the April 2019 FDA clearance of Plenity, we received a clear indication that Plenity can be prescribed for patients for an unlimited amount of time — therefore, we believe no additional data or studies are required to support the long-term use of Plenity.

In terms of additional indications that we may pursue, we have completed, and plan to complete, additional studies to support gaining FDA clearance for these indications. A six-month study examining the impact of one of our hydrogels on patients with pre-diabetes or diabetes with respect to weight loss was recently completed and, as of the date of this prospectus, the results remain under analysis as described below. The two primary endpoints of this study are: 1) the proportion of subjects who achieve weight loss ≥5.0%, and 2) the average percent change in total body weight. In both cases the outcome for subjects on our hydrogel (i.e., GS200) are compared to the outcomes for subjects on placebo at the end of the six-month study. These two weight loss metrics are standard for weight studies designed for FDA review. We are still evaluating whether the outcome results of this study will support FDA authorization for these specific populations or if further studies are advisable.

Our Other Product Candidates

Our proprietary hydrogel technology allows the flexibility to specifically engineer the hydrogel structure to have different physical properties (e.g., elasticity, media uptake ratio or volume, and hydration speed) that could potentially benefit multiple GI-related and chronic metabolic diseases including pre-diabetes (which occurs in approximately 30% of the adult population), type 2 diabetes (which occurs in approximately 10% of the population), NAFLD/NASH (occurring in 25% of the adult population), and FC (occurring in 14% of the adult population). Each of our pipeline candidates are likely to be regulated by the FDA through the *de novo* classification or 510(k) pathways.

The following table summarizes the current and expected development status of our product candidates.



GS200 for Weight loss in Prediabetes and Type 2 Diabetes

Because people classified as having obesity are much more likely to develop type 2 diabetes, the increase in obesity rates has contributed significantly to the increase in the number of patients diagnosed with type 2 diabetes (defined by a fasting blood glucose level ≥ 126 mg/dL). According to the American Diabetes Association, or ADA, diabetes was the seventh leading cause of death by disease in the United States in 2017. In 2018, approximately 30.7-32.5 million Americans suffered from type 2 diabetes and 89% of U.S. adults diagnosed with diabetes were overweight or had obesity. An additional 88 million American adults 20 years of age and older were considered as having prediabetes (defined by a fasting blood glucose level ≥ 100 mg/dL and < 126 mg/dL), with approximately 1.5 million new diagnoses of type 2 diabetes per year. Based on current trends, as many as one in three Americans will develop type 2 diabetes in their lifetime. According to the ADA, the economic impact of diagnosed diabetes was estimated to be $327 billion in 2017, approximately $237 billion of which was attributed to direct medical costs, and approximately $90 billion of which was attributed to reduced productivity.

The current treatment paradigm for prediabetes and type 2 diabetes focuses on lifestyle changes, in particular weight loss, as a foundational therapy — as weight loss alone is associated with improvements in glycemic parameters and prevention of the progression from prediabetes to diabetes. Medications to manage blood glucose levels are also prescribed for patients with diabetes. Surprisingly, weight loss therapies are generally not commonly prescribed to these patient populations. Only 2% of people who have excess weight or obesity receive weight loss therapies, and many of these patients have prediabetes or diabetes.

GS200 is a hydrogel similar in concept to Plenity, but has different physical properties that we believe could address different indications and treatment regimens. When compared to Plenity, GS200 hydrates more rapidly and creates a higher elastic response while it occupies a slightly smaller volume in the stomach. For example, due to its higher elastic response and accelerated hydration, GS200 could be more suitable for glycemic control, where one relevant mechanism is the delay of the absorption of glucose in the small intestine. For this purpose, the volumetric effect at the beginning of the meal could be less important and GS200 could be administered immediately prior to the meal. We believe that these properties could make GS200 more suitable as a weight loss and glycemic control product for prediabetics and type 2 diabetics. GS200 is currently being evaluated in a human study where the primary endpoints are weight loss and some of the secondary endpoints are related to glycemic control. We are presently reviewing the data reported in this study.

GS200 clinical study overview and reported data

We completed a preliminary analysis of the LIGHT-UP study, a multicenter, randomized, double-blind, placebo-controlled, investigational study that enrolled 254 subjects with overweight or obesity who also have prediabetes or type 2 diabetes, and that analysis remains underway. The study was designed to assess the change in body weight in adults after six months of treatment with a new oral superabsorbent hydrogel (GS200) or placebo. The study met both of its primary endpoints: the proportion of participants who achieved at least 5% body weight loss (defined as “Responders”) and the change in body weight as compared to placebo after six months of therapy.

Among the participants who completed the study protocol requirements, or the per protocol (“PP”) population, 64% of GS200-treated participants were Responders vs. 41% in the placebo group (p=0.001). Including data from participants who did not complete the study, or the intent-to-treat multiple imputation (“ITT-MI”) population, in the preliminary analysis, 55% of GS200- treated participants were Responders vs. 34% in the placebo group (p=0.0004). The average body weight loss of the Responders was 11% (approximately 23 pounds) and their waist circumference was reduced by 5.5 inches on average. Importantly, GS200 treated participants had 2.8 higher odds as compared to placebo to become Responders (adjusted odds ratio [OR]: 2.83, P=0.0004), achieving the first primary endpoint of the study.

With respect to average total weight loss, the complete GS200 treatment group (including both Responders and non-Responders) demonstrated superiority over placebo after 6 months of treatment (body weight loss of 6.9% vs. 4.1%, P=0.0003 in the PP population and 6.3% vs. 3.6%, P=0.0006 in the ITT-MI population), thereby achieving the second primary endpoint.

This study was conducted at 36 clinical sites in Europe and North America with 208 subjects who completed the 6-month study. Upon preliminary regional analyses, both primary endpoints were met across the entire ITT-MI and PP populations and were also highly significant in Europe alone (N=134 completers). In North America alone, there was no difference between GS200 and placebo with respect to the primary endpoints. The North American region included approximately half the number of subjects who completed the study compared to Europe (N=74 completers). While the primary endpoints were met, Gelesis continues to analyze this data and the insights it may derive as it plans its next steps in the development of GS200 and final plans to present the detailed results in a scientific venue.

Less than 2% of the GS200 treated participants dropped out of the LIGHT-UP study due to adverse events (AEs), which was similar to the dropout rate in the placebo group. There were no statistically significant differences in the incidence and severity of AEs between the two groups except for the overall incidence of gastrointestinal-related AEs, which was slightly higher in the GS200 group. No serious adverse events related to GS200 were observed and 95% of all AEs in the GS200 group were mild or moderate in intensity.

GS200 as a weight management food supplement

We are exploring opportunities of utilizing GS200 as a food supplement or added to different types of foods, such as food bars or other nutritional products. The building blocks of the Gelesis hydrogel platform are consumed as foods and considered by the FDA as generally regarded as safe or “GRAS”. This pedigree provides an opportunity to develop GS200 as a supplement and potentially apply to products that do not go through the FDA regulatory drug or device process. Gelesis already has developed multiple prototype food bars and has the ability to quickly adapt the delivery vehicle to make it easy to consume.

GS500 for Functional Constipation (formerly known as chronic idiopathic constipation)

FC is a health condition in which a person experiences chronic symptoms of constipation without an identifiable cause. It is one of the most common gastrointestinal disorders worldwide, with a global prevalence of 14% in adults. In the United States, approximately 35 million adults may suffer from FC. Lifestyle modifications, including increasing dietary fiber, hydration and exercise, are the first step in managing FC. If patients do not respond to these lifestyle modifications, then treatment with osmotic and stimulant laxatives (mostly over-the-counter products) are often used. Approximately 50% of patients do not find these traditional laxatives to be satisfactory and seek other solutions. Prescription options sometimes are offered to patients that do not respond to traditional laxatives, but these options have common side effects (e.g., diarrhea).

Existing prescription options include Amitiza (lubiprostone), Linzess (linaclotide), Trulance (plecanatide) and Motegrity (prucalopride). All of these drug therapies work by entering the patient's blood stream.

Similar to Plenity, our superabsorbent hydrogel candidate GS500 has a unique non-systemic mechanism of action and works locally in the GI tract. If proven safe and effective, GS500 has the potential to become a new approach to treat FC. In an investigator sponsored study conducted by researchers at the Massachusetts General Hospital, GS500 demonstrated statistically significant benefit in decreasing colon transit time. We plan to advance GS500 into a pivotal 12-week global study that is expected to enroll 260 subjects with FC and compare the effectiveness of GS500 to a placebo. We anticipate top line results in the fourth quarter of 2024.

Sales and Marketing

Plenity is, and our future product candidates, if approved, may, be marketed, detailed, and presented through the same channels as orally administered weight loss pharmaceuticals. Plenity is, and our future product candidates, if approved, may be prescribed predominantly by primary care physicians, including general practitioners, family practitioners, and internists, as well as endocrinologists and obesity/metabolism specialists.

We have partnered with Roman Health Pharmacy ("Ro"), a leading telehealth platform in the United States, to provide convenient and immediate access to physicians online at no cost. We have entered into an agreement with Ro, giving it exclusive telehealth distributor rights to sell Plenity via telehealth in the United States through June 2023. Pursuant to the terms of the agreement, we have no obligations or commitments beyond the sale and supply of Plenity to Ro. Pursuant to the terms of the agreement, Ro has no obligations or commitments specifically with respect to marketing and promotional spend in support of the sale of Plenity to consumers.

We have established partnerships with behavioral weight management companies such as WW International, Inc. and Noom, providing members access to WW's behavioral weight management program and supporting lifestyle content and offering discounts to Noom's subscription programs. To further develop our commercial infrastructure, we may establish additional alliances with additional biotechnology or pharmaceutical company collaborators, depending on, among other things, the applicable indications, the related development costs, and our available resources.

Our ability to expand our customer base through sales and marketing efforts and generate related revenue is dependent upon our ability to successfully raise additional capital to fund such efforts. Our failure to obtain additional funding may force us to delay, limit or terminate some or all of our sales and marketing efforts, which may negatively impact our ability to acquire sufficient customers to operate profitably.

Plans to Make Plenity Available Without a Prescription

We believe Plenity's advantages are its differentiated safety-to-efficacy profile, broad approved labeling, and affordability to the consumer. Accordingly, we believe it is important that Plenity be widely available and easily accessible to consumers. In addition to making Plenity more accessible to people struggling with excess weight, we believe making Plenity available OTC could reduce costs associated with acquiring new members and allow us to reduce costs associated with the prescription granting process, while also enabling new sales channels for us. In January 2023, we submitted a 510(k), or premarket notification, to the FDA to change Plenity's classification in the United States from prescription-only to OTC and anticipate the FDA's decision on our 510(k) submission by the third quarter of 2023.

Competition

Due to the growing overweight and obesity epidemic and consumer demand, there are many competitors in the field of obesity treatment. Obesity treatments range from behavioral modification, to drugs and medical devices, and surgery, generally as a last resort. Although Plenity regulated as a novel medical device, it can be used by patients and prescribed by physicians in the same manner as an orally administered drug. Because of Plenity's unique product profile and go-to-market strategy, also considering the significant clinical inertia not to treat overweight and obesity, we expect Plenity to become a foundational approach for weight management and be positioned to work synergistically with other approaches rather than being a direct competition.

Orally Administered Drugs

Three oral drugs that are FDA approved and currently marketed for the treatment of obesity are phentermine/topiramate, naltrexone/bupropion, and orlistat. Each treatment is indicated for patients with overweight and obesity with at least one comorbidity. In September 2012, Vivus, Inc. commercially launched its combination product, Qsymia (phentermine/topiramate) in the United States. In October 2014, Takeda Pharmaceutical Company Limited commercially launched its combination product, Contrave (naltrexone/ bupropion), in the United States. Contrave is currently marketed in the United States by Currax Pharmaceuticals LLC. Orlistat is currently marketed in the United States by H2-Pharma, LLC under the brand name Xenical and over-the-counter at half the dose of Orlistat by GlaxoSmithKline plc under the brand name alli. In addition to competing with one another, these drugs also compete against generic forms of phentermine, topiramate, naltrexone, and bupropion.

Injectable Drugs

Several pharmaceutical companies, have or are developing injectable drugs for obesity. Saxenda, a formulation of Novo Nordisk's liraglutide, was approved by the FDA in December 2014 for the treatment of obesity. Liraglutide is currently also marketed by Novo Nordisk for the treatment of type 2 diabetes under the brand name Victoza in the United States. Wegovy, a sub-cutaneous formulation of Novo Nordisk's semaglutide was approved by the FDA in June of 2021. Tirzeptide, marketed by Lilly under the brand name Mouniaro, was approved by the FDA in May 2022 for adults living with type 2 diabetes and is currently in phase III development for obesity.

Medical Devices and Surgery

Other than Plenity, four types of FDA-regulated devices are currently marketed for weight loss. Intragastric balloon manufacturers including Apollo EndoSurgery, Inc. and Obalon Therapeutics, Inc. commercialize ORBERA Balloon and the Obalon Balloon, respectively. Aspire Assist, manufactured by Aspire Bariatrics, Inc., is a gastric emptying system that allows patient to aspirate digested food after a meal. SmartByte, manufactured by Scientific Intake Limited Co., is a device that is designed to occupy space in the roof of the mouth to reduce food intake. LAP-BAND Adjustable Gastric Banding System, manufactured by BioEnterics Corporation, is a gastric band that is placed around the upper part of the stomach in a surgical procedure leaving only a small pouch available for food.

Bariatric surgery, including gastric bypass, gastric sleeve and gastric banding procedures, is typically employed for patients with obesity with a BMI exceeding 40 or those with a BMI greater than 35 who are experiencing obesity-related complications such as type 2 diabetes, high blood pressure or severe sleep apnea.

Reimbursement

We believe the successful launch of our products and product candidates will not be dependent on reimbursement from third-party payors, such as government health programs and private insurance companies and we do not expect any such direct reimbursement to be available at this time. Accordingly, our strategy and business plan do not contemplate any such reimbursement. Although obesity has long been recognized as a significant public health and economic problem for the U.S. healthcare system, insurance coverage for obesity treatments has been limited. The legislative authorization for Medicare's prescription drug benefit program specifically prohibits coverage of obesity drugs and until recently, there has been little clinical evidence to convince insurers of the efficacy of obesity treatments, let alone coverage for dietary regimens and products. When coverage is provided by insurers, such as for treatments such as bariatric surgery, it is typically limited to patients with morbid obesity. For reasons noted elsewhere herein, we believe that our commercialization strategy, which does not rely on third-party-payor reimbursement, has a number of significant strategic advantages for us.

Government Regulation

General Requirements for Regulation of Medical Devices in the United States

Under the Federal Food, Drug, and Cosmetic Act, or the FDC Act, a medical device is an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component part, or accessory which is: (i) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; (ii) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (iii) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

In the United States, medical devices are subject to extensive regulation by the FDA under the FDC Act, and its implementing regulations, and certain other federal and state statutes and regulations. The laws and regulations govern, among other things, the research and development, design, testing, manufacture, packaging, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution and import and export of medical devices. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as FDA refusal to approve pending premarket approval applications, or PMAs, issuance of warning letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

The FDC Act classifies medical devices into one of three classifications based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices must typically be approved by the FDA before they are marketed.

Generally, establishments that manufacture and/or distribute devices, including manufacturers, contract manufacturers, sterilizers, repackagers and relabelers, specification developers, reprocessors of single-use devices, remanufacturers, initial importers, manufacturers of accessories and components sold directly to the end user, and U.S. manufacturers of export-only devices, are required to register their establishments with the FDA and provide the FDA a list of the devices that they handle at their facilities.

Pre-market Approval and Pre-market Notification

While most Class I and some Class II devices can be marketed without prior FDA authorization, most medical devices can be legally sold within the United States only if the FDA has: (i) approved a PMA application prior to marketing, applicable to Class III devices for which the FDA has required a PMA; or (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class II and some Class I devices. Some devices that have been classified as Class III are regulated pursuant to the 510(k) requirements because FDA has not yet called for PMAs for these devices. Other less common regulatory pathways to market for Class III devices include the humanitarian device exception, or HDE, or a product development protocol, or PDP.

510(k) Pre-market Notification Most Class II and limited Class I devices require a 510(k) clearance in order to be commercially distributed in the United States. To obtain 510(k) clearance, a manufacturer must submit a premarket notification to the FDA demonstrating that the proposed device is substantially equivalent to a legally marketed device, referred to as the predicate device. A predicate device may be a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet required submission of PMA applications. The manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or it is shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device.

There are three types of 510(k)s: traditional, special and abbreviated. Special 510(k)s are for devices that are modified and the modification needs a new 510(k) and the methods used to evaluate the changes are well established, and the results can be sufficiently reviewed in a summary or risk analysis format. Abbreviated 510(k)s are for devices that conform to a recognized standard. The special and abbreviated 510(k)s are intended to streamline review. The FDA intends to process special 510(k)s within 30 days of receipt, and abbreviated 510(k) within 90 days of receipt.

Though statutorily required to clear a traditional 510(k) within 90 days of receipt, the clearance pathway for traditional 510(k)s can take from four to 12 months, or even longer.

De Novo Classification Devices of a new type that FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513(f)(1) of the FDC Act, regardless of the level of risk they pose. To avoid requiring PMA review of

low-to moderate-risk devices classified in Class III by operation of law, Congress enacted section 513(f)(2) of the FDC Act. This provision allows FDA to classify a low-to moderate-risk device not previously classified into Class I or II. The *de novo* process has been infrequently used. In 2012, Congress amended the process to potentially make it more amenable to FDA and industry. It is not yet clear whether the changes will lead to greater use of *de novo* classification.

PMA Approval For Class III devices for which the FDA has required a PMA, a PMA application must be submitted to the FDA with proof of the safety and effectiveness of the device to the FDA's satisfaction. The cost of preparing and submitting a PMA is substantial. Under federal law, the submission of most PMAs is additionally subject to a substantial annually-adjusted application user fee, currently exceeding $250,000. Satisfaction of FDA premarket approval requirements typically takes years and the actual time required may vary substantially based upon the type, complexity, and novelty of the device or disease.

Results from adequate and well-controlled clinical trials are required to establish the safety and effectiveness of a Class III PMA device for each indication for which FDA approval is sought. After completion of the required clinical testing, a PMA including the results of all preclinical, clinical, and other testing, and information relating to the product's marketing history, manufacture, and controls, is prepared and submitted to the FDA.

Upon submission, the FDA determines if the PMA application is sufficiently complete to permit a substantive review, and, if so, the application is accepted for filing. The FDA then commences an in-depth review of the PMA application, which typically takes one to three years, but could take longer. The review time is often significantly extended as a result of the FDA asking for additional information or clarification of information already provided. During the review period, an FDA advisory committee, typically a panel of clinicians, may be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. Although the FDA is not bound by the advisory panel decision, the panel's recommendation is important to the FDA's overall decision making process. The FDA will also typically inspect one or more clinical sites to assure compliance with FDA regulations. Additionally, the FDA will inspect the facility or the facilities at which the device is manufactured. FDA will not approve the device unless compliance is shown with Quality System Requirements ("QSR"), which impose elaborate testing, control, documentation and other quality assurance procedures.

Upon completion of PMA review, the FDA can: (i) approve the PMA; (ii) issue an approvable letter which indicates the FDA's belief that the PMA is approvable and states what additional information the FDA requires, or the post-approval commitments that must be agreed to prior to approval; (iii) issue a not approvable letter which outlines steps required for approval, but which are typically more onerous than those in an approvable letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (iv) deny the application. If the FDA issues an approvable or not approvable letter, the applicant has 180 days to respond, after which the FDA's review clock is reset.

An approval order authorizes commercial marketing of the device with specific prescribing information for one or more specific indications, which can be more limited than those originally sought by the manufacturer. As a condition of PMA approval, the FDA may restrict the sale, distribution, or use of the device to help ensure that the benefits of the device outweigh the potential risks. Moreover, FDA may impose substantial post-approval testing and post-market surveillance to monitor the device's safety or effectiveness. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Once granted, FDA has the authority to withdraw device approvals if compliance with regulatory requirements is not maintained or problems are identified following initial marketing.

An "approvable letter" generally requires the applicant's agreement to specific conditions, e.g., changes in labeling, or specific additional information, e.g., submission of final labeling, in order to secure final approval of the PMA application. Once the approvable letter is satisfied, the FDA will issue a PMA for the approved indications.

Exempt Devices If a manufacturer's device falls into a generic category of Class I or Class II devices that FDA has exempted by regulation, a premarket notification is not required before marketing the device in the United States. Manufacturers of such devices are required to register their establishments and list the generic category or classification name of their devices. Some 510(k)-exempt devices are also exempt from QSR, except for the QSR-complaint handling and recordkeeping requirements.

Pre-Submission Meetings The FDA has mechanisms to provide companies with guidance prior to formal submission of either a 510(k) or PMA. One such mechanism is the pre-submission program in which a company has a "pre-submission" meeting as outlined in the FDA guidance document "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with the Food and Drug Administration Staff" that was issued on February 18, 2014. The main purpose of the pre-submission meeting is to provide companies with guidance from the FDA on matters of significance to an approval decision. Prior to the pre-submission meeting, the company provides a briefing document to the FDA. The FDA is not obligated to follow the recommendations it provides to companies as a result of a pre-submission meeting.

Clinical Trials

A clinical trial is almost always required to support a PMA application or *de novo* submission and is sometimes required for a premarket notification. For significant risk devices, the FDA regulations require that human clinical investigations conducted in the United States be approved via an Investigational Drug Exemption or IDE, which must become effective before clinical testing may commence. A nonsignificant risk device does not require FDA approval of an IDE; however, the clinical trial must still be conducted in compliance with various requirements of FDA's IDE regulations. In some cases, one or more smaller studies may precede a pivotal clinical trial intended to demonstrate the safety and effectiveness of the investigational device. A 30-day waiting period after the submission of each IDE is required prior to the commencement of clinical testing in humans. If the FDA determines that there are deficiencies or other concerns with an IDE that require modification, the FDA may permit a clinical trial to proceed under a conditional approval. If the FDA disapproves the IDE within this 30-day period, the clinical trial proposed in the IDE may not begin.

An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must also include a description of product manufacturing and controls, and a proposed clinical trial protocol. FDA typically grants IDE approval for a specified number of patients to be treated at specified study centers. During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and record keeping requirements. The IDE requirements apply to all investigational devices, whether considered a significant or nonsignificant risk.

Prior to granting PMA approval, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements.

Clinical trials must be conducted: (i) in compliance with federal regulations, including those related to good clinical practices, or GCPs, which are intended to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors; and (ii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Clinical trials are typically conducted at geographically diverse clinical trial sites, and are designed to permit FDA to evaluate the overall benefit-risk relationship of the device and to provide adequate information for the labeling of the device. Clinical trials, for significant and nonsignificant risk devices, must be approved by an institutional review board, or IRB, for each trial site. An IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving patients and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety, and welfare of human research subjects.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that FDA may impose with respect to manufacturing.

Investigational devices may only be distributed for use in an investigation, and must bear a label with the statement: "CAUTION — Investigational device. Limited by Federal law to investigational use."

Disclosure of Clinical Trial Information

Sponsors of clinical trials of medical devices are required to register with clinicaltrials.gov, a public database of clinical trial information, and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed until the product being studied has been approved. For medical device clinical trials, public availability of study registration information can also be delayed until approval of the device. Competitors may use this publicly-available information to gain knowledge regarding the design and progress of our development programs.

Post-market Requirements

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the FDA's general prohibition against promoting products for unapproved or "off-label" uses, the Medical Device Reporting regulation, and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act).

FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions, and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing requests for 510(k) clearance or PMA approval of new products;
- withdrawing PMA approvals already granted; and
- criminal prosecution.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Device Modifications

Some changes to an approved PMA device, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new PMA or PMA supplement, as appropriate, before the change can be implemented. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA. The FDA uses the same procedures and actions in reviewing PMA supplements as it does in reviewing original PMAs.

Modifications to a device that received 510(k) clearance may require a new 510(k) submission if those changes could significantly affect the safety or effectiveness of the device, or if the modifications represent a major change in intended use. If the manufacturer determines that a modification could not substantially affect the safety or effectiveness of the device, it should document the changes and rationale for not submitting a new 510(k). Though the manufacturer is responsible for the initial assessment, FDA may disagree, and later require the manufacturer to submit a 510(k) for the modified device. FDA could require the manufacturer to cease marketing the modified device during the pendency of the 510(k) clearance process.

Adverse Event Reporting and QSR Compliance

Following FDA approval of a PMA or 510(k) clearance, the device sponsor must submit reports to FDA regarding adverse events. Under the Medical Device Reporting regulation, manufacturers must report to the FDA if their device may have caused or contributed to a death or serious injury or if a malfunction occurred that would be likely to cause or contribute to a death or serious injury if it were to recur. For a PMA or Class II 510(k) device, the FDA also may require device tracking, and post-market surveillance to monitor the effects of an approved or cleared product. The FDA may also require post-market studies. In addition, quality-control, manufacture, packaging, and labeling procedures must continue to conform to the QSR after approval and clearance. FDA is required by the FDC Act to inspect device manufacturers every 2 years to assess compliance with the QSR, although FDA does not always adhere to this schedule. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with the QSR. The FDA may withdraw product approvals or recommend product recalls if a company fails to comply with regulatory requirements. FDA has the authority to conduct mandatory recalls, but that authority is rarely used.

Regulation of the Practice of Medicine and Telehealth in the United States

An important element of our direct-to-consumer approach is providing consumer access through telehealth platforms. The practice of medicine, including telehealth medicine, is subject to various federal, state and local certification and licensing laws, regulations, approvals and standards, relating to, among other things, the qualifications of the provider, the practice of medicine (including specific requirements when providing health care utilizing telehealth technologies and the provision of remote care), the continuity and adequacy of medical care, the maintenance of medical records, the supervision of personnel, and the prerequisites for the prescription of medical devices such as Plenity. Because the practice of telehealth is relatively new and rapidly developing, regulation of telehealth is evolving and the application, interpretation and enforcement of these laws, regulations and standards can be uncertain or uneven. However, as of now, interpretation of the state medical boards policy in all fifty states permit the prescribing of Plenity through telehealth platforms, and Plenity is being made available through telehealth platforms in all fifty states.

Advertising, Promotion, Anti-Kickback Statute, False Claims Laws, and Other Healthcare Regulatory Laws

A device may be marketed only for the indications for use for which it was approved or cleared.

In addition to FDA restrictions on marketing of devices, device companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and transparency laws and regulations related to pricing and payments and other transfers of value made to physicians and other healthcare providers. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and responsible individuals may be subject to imprisonment.

Regulatory Considerations for Outside the United States

In the European Union medical devices were previously regulated under Directive 93/42/EEC, also known as the Medical Device Directive, or MDD, and the implementing legislation in each Member State of the European Union, or EU. On May 26, 2021, Regulation 2017/745, also known as the Medical Devices Regulation, or MDR, became fully available. The MDR repealed the MDD and was, among other things, intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation.

In order to be sold in the Member States of the EU, medical devices must comply with the general safety and performance requirements of the MDR (previously, the essential requirements of the MDD) and therefore be entitled to bear the Conformité Européene, or CE, marking, without which they cannot be sold. The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The method of assessing conformity varies depending on the risk class of the device. Devices can fall under Class I (lowest risk), Class IIa, Class IIb and Class III (the highest risk). Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the general safety and performance requirements of the MDR, a conformity assessment procedure requires the intervention of an independent organization accredited by a Member State of the European Union to conduct conformity assessments, known as a notified body. Depending on the device's class, the manufacturer may submit a technical file to a notified body that demonstrates consistency with the general safety and performance requirements under the MDR. Class III devices also require submission of a design dossier. Demonstrating consistency with the MDR's requirements may entail the manufacturer providing both pre-clinical as well as human data form clinical trials. The notified body's assessment also may consist of an audit of the manufacturer's quality system or specific testing of the manufacturer's product. A number of notified bodies exist in the EU and the sponsoring company is responsible for choosing the notified body. The notified body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the general safety and performance requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

Under the MDR, conformity assessment certificates issued under the MDD prior to May 25, 2017 until May 25, 2021 will remain valid in accordance with their term, but shall not exceed five years and shall become void after May 26, 2024. However, in response to concerns raised about notified body capacity and the ability for devices to be re-certified within such time period, the European Commission has adopted a proposal to extend the transition period by some years, depending on the risk class of the device. Such proposal is currently being considered for adoption by the European Parliament and Council.

In order for devices to be sold in the EU, a quality management system, or QMS, must be put in place that is consistent with certain sets of standards set by the International Standards Organization, or ISO, such as ISO 13485. The QMS must be audited prior to Gelesis100 obtaining a CE mark. In the EU, manufacturing, sales, promotion and other activities following product approval are also subject to regulation by competent authorities.

Following the UK's departure from the EU on January 31, 2020, the UK (which comprises Great Britain and Northern Ireland) continued to follow the same regulations as the EU during a transition period which ended on December 31, 2020. Now that this transition period has ended, all medical devices must be registered with the Medicines and Healthcare products Regulatory Agency, or MHRA, before being placed on the Great Britain (GB) market and a new UKCA Mark was introduced for medical devices placed on the GB market. European CE marks will continue to be recognized in GB until June 30, 2024, following which transitional arrangements will apply before all devices will be required to have a UKCA mark to be marketed in GB. The MDR does not apply in GB and, now that GB and EU regulatory systems are independent, the regulation of medical devices in GB may diverge more significantly from EU regulations in the future. The EU regulatory framework on medical devices does, however, continue to apply in Northern Ireland under the Northern Irish Protocol and medical devices in Northern Ireland may either carry a European CE mark or a CE UKNI mark (although devices bearing the CE UKNI marking will not be accepted on the EU market).

Although some other countries outside of the United States and the EU may accept either FDA approval or a CE mark as a basis for regulatory approval, many countries, e.g., Japan, have their own requirements in order for a device to be marketed. In order to market its products in those countries, Gelesis would need to submit the appropriate applications and meet the requirements set by those regulatory agencies.

As is the case in the United States, the failure to comply with regulatory requirements in foreign countries subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. New information regarding the safety or effectiveness of a product could result in either increased regulatory requirements or change the ability of Gelesis to access markets.

License Agreements

One S.r.l.

In October 2008, we entered into a patent license and assignment agreement and master agreement with One S.r.l., or One, and certain inventors to license and subsequently purchase certain intellectual property, including core patents that cover our superabsorbent hydrogel technology. One and the inventors are bound by non-competition provisions, which prohibit them from developing, manufacturing or commercializing any product or process related to diet, weight loss, food products or obesity during the term of our agreement and for a year after its termination. Additionally, the inventors have agreed to assign to us certain future technology relating to food products that they develop during the term of the agreement, as well as other improvements to our existing intellectual property rights that result from certain activities they perform for us.

In October 2020, we last amended and restated the agreement with One, pursuant to which we are required to pay One a 2.0% royalty on net product sales and €17.5 million upon the achievement of certain milestones and pay royalties on future sales and/or a percentage of sublicense income.

In August 2022, we entered into an amendment to the Warrant Purchase Agreement dated October 21, 2020, by and between us and the holders of the warrants. Pursuant to the amendment, we deferred payment of the aggregate remaining purchase price under the patent license and assignment agreement and master agreement between us and One S.r.l., totaling €2.5 million, owed to One S.r.l. shareholders until March 31, 2023.

Pursuant to the amendment, and in consideration for the deferral, we amended the exercise price of the One S.r.l. warrant holders' 1,353,062 previously issued common stock warrants from $4.26 to $1.45.

China Medical System (CMS)

In June 2020, we and CMS Bridging DMCC, a subsidiary of China Medical Systems Holdings Limited, or CMS, entered into a set of licensing, collaboration, and investing agreements, or CMS Agreements, involving the license of our intellectual property to CMS in Greater China (including Mainland China, Hong Kong, Macau, and Taiwan), Singapore and United Arab Emirates, or the CMS Territory, and governing the supply of Plenity to CMS for sale in the CMS Territory. Under the terms of the CMS Agreements, we granted CMS an exclusive, transferable, sublicensable, and royalty-bearing license of our intellectual property to develop, import,

register, manufacture, and commercialize Plenity, whether through online sales channels or offline sales channels during the term of the CMS Agreements. In accordance with the CMS Agreements, all legal and beneficial ownership of (i) all intellectual property rights relating to Plenity (including any data generated from the use of Plenity and other improvements) and (ii) all of the information provided or generated under the CMS Agreements or otherwise related to Plenity shall both ultimately belong to and remain vested with us. CMS must purchase Plenity at a markup of our cost of goods sold.

As consideration for the rights and licenses granted to CMS under the CMS Agreements, CMS paid us a one-time, non-refundable and non-creditable upfront fee of $15.0 million and is required to pay a one-time, non-refundable, and non-creditable milestone payment of $5.0 million within thirty (30) days after the earlier of (i) the approval of marketing authorization of Plenity as a prescription product by the National Medical Products Administration, and (ii) the fifth (5th) anniversary of the CMS Agreements' effective date. The CMS Agreements also contain commercial milestones of up to $388 million in the aggregate, due to us based on the achievement of annual net product revenue thresholds in the CMS Territory. Additionally, CMS will pay us royalties on net sales of all our products sold in the CMS Territory commencing January 1, 2022 through the expiration date of the CMS Agreements.

In August 2022, we entered into an amendment to CMS Agreements, pursuant to which the one-time, non-refundable, and non-creditable regulatory approval milestone payment of $5.0 million provided for in the original agreement became immediately payable. In addition, the amendment expands the CMS Territory to include Brunei, Myanmar, Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Thailand and Vietnam and provides that the minimum annual royalty term for CMS territory will commence January 2024 (rather than January 2022, as previously provided under the original agreement) and extend through the expiration date of the amended agreement.

Upon execution of the amendment, we also issued to CMS a warrant to purchase up to 400,000 shares of common stock, par value $0.0001 per share, at an exercise price of $0.01 per share. The warrant expires on the date that is ten years from the date of issuance and is exercisable at any time from the date of issuance until the expiration date.

PureTech Health

In December 2009, we entered into a royalty and sublicense income agreement with PureTech Health LLC, or PureTech, under which we are required to pay PureTech a 2.0% royalty on net product sales received as a result of developing hydrogel-based products and technology using the intellectual property we license from PureTech. The royalty rate is subject to certain downward adjustments in the event we are required to pay third parties to obtain a license to intellectual property rights that are necessary for us to develop or commercialize our products. Our obligation to pay royalties to PureTech will terminate upon termination of our license agreement with One.

Trade Secrets

Our proprietary superabsorbent hydrogel technology is also protected as trade secrets, which cover a variety of aspects of our operations. Our trade secrets may include manufacturing operations and other business processes. We use a variety of means to protect our trade secrets, including entering into confidentiality agreement with employees and third parties.

Trademarks and Domain Names

We have trademark rights and registrations in our name, logo, and other brand indicia in the United States and other jurisdictions around the world. We also have registered domain names for websites that we use in our business, such as www.gelesis.com, and www.myplenity.com.

Human Capital Resources

As of December 31, 2022, Gelesis employed 93 full-time employees and 7 consultants. We have never had a work stoppage, and none of our employees is represented by a labor organization. We consider our employee relations to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy and information statements and amendments to reports filed pursuant to Sections 13(a), and 15(d) of the Securities Exchange Act of 1934, as amended

(the Exchange Act) are filed with the U.S. Securities and Exchange Commission (SEC). We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements and other information with the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. Such documents and other information filed by us with the SEC are available free of charge on the Investor section of our website when such reports are available on the SEC's website.

Item 1A. Risk Factors.

An investment in our securities involves a high degree of risk. You should consider carefully all of the risks described below, together with the other information contained in this Form 10-K and our other filings with the SEC, before making a decision to invest in our securities. If any of the following events occur, our business, financial condition and operating results may be materially adversely affected. In that event, the trading price of our securities could decline, and you could lose all or part of your investment.

Summary of Principal Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted below, which illuminate challenges that we face in connection with the successful implementation of our strategy and the growth of our business. The following considerations, among others, may offset our competitive strengths or have a negative effect on our business strategy, which could cause a decline in the price of shares of our securities and result in a loss of all or a portion of any investment in our securities:

Risks Related to Financial Position and Financing Needs

- We have generated limited product sales to date and incurred significant operating losses since our inception and we anticipate that we will continue to incur continued losses for the next several years.
- We may be unable to accurately forecast revenue and appropriately plan our expenses in the future.
- In order to support our business, we will need to incur additional indebtedness or seek capital through new equity or debt financings, which sources of additional indebtedness or capital have become increasingly difficult to secure and may not be available on acceptable terms, if at all, and the failure to obtain this additional funding when needed may force us to delay, limit or terminate our product development efforts or other operations.
- We believe our current cash and cash equivalents will not be sufficient to fund our business for the next twelve months from the date of the unaudited consolidated financial statements included elsewhere in this Form 10-K, raising substantial doubt about our ability to continue as a going concern.

Risks Related to Product Development, Regulatory Approval and Commercialization

- We are dependent on the success of our hydrogel technology for Plenity, which is currently our only marketed and FDA-authorized product.
- Plenity may cause undesirable side effects that could result in significant negative consequences, including product liability or other litigation, that may be costly to us and/or adversely impact the commercial success of Plenity. The broad prescription pharmaceutical and medical device market for overweight and obesity is strictly regulated.
- We are, and will continue to be, subject to ongoing and extensive regulatory requirements. Any failure to comply with applicable laws and regulations, including those pertaining to the advertising and promotion of healthcare products, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings, and substantially harm our business.
- Plenity is currently regulated as a medical device by the FDA and may become subject to similar or other therapeutic regulatory requirements outside the United States.
- Recently enacted and future legislation may increase the difficulty and cost for us to further commercialize Plenity and any other products we may develop in the future and decrease the prices we may obtain for our approved products.
- We are responsible for manufacturing Plenity and will continue to invest in manufacturing capacity to meet potential increases in demand. Our inability to produce an adequate supply of Plenity, due to the loss of these facilities or other future facilities or any material limitation of production at these facilities, could materially and adversely impact the commercial growth and success of Plenity and, consequently, could cause our revenue, earnings or reputation to suffer.
- There is no guarantee that we will be able to successfully commercialize Plenity through the channels, or in the markets, we are targeting or at all.
- The telehealth market is immature and volatile, and if it does not develop, if it develops more slowly than we expect, or if it encounters negative publicity, our ability to fully commercialize Plenity and grow our business will be harmed.
- Successful commercialization of Plenity is dependent on the willingness of the ultimate patient to pay out-of-pocket. If there is not sufficient patient demand for Plenity, our financial results and future prospects will be harmed.
- Competing products and technologies could emerge, including pharmaceuticals, devices, and surgical procedures, that adversely affect our opportunity to generate sales of Plenity and achieve profitability.

Risks Related to Intellectual Property Rights

- If we are unable to adequately protect our proprietary technology or maintain issued patents that are sufficient to protect Plenity, or if competitors are able to market competitive products without infringing our protected intellectual property rights, others could compete against us in ways that would have a material adverse impact on our business, results of operations, financial condition and prospects.
- We have licensed Plenity to third party partners and have also granted limited licenses to practice patent rights for noncommercial, research purposes. We may continue to out-license our intellectual property and may agree under certain circumstances to grant limited exclusive or non-exclusive commercial rights as well. There can be no guarantee that the third party's activities will not in any way overlap or interfere with the commercialization of Plenity. Additionally, there is always the possibility that we may become dependent on obtaining access to third party intellectual property in connection with the commercialization of Plenity or for other new product candidates in the future.
- We may infringe the intellectual property rights of others, which may prevent or delay our development efforts or stop us from commercializing or increase the costs of commercializing Plenity.
- We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time- consuming, and unsuccessful.
- Issued patents covering Plenity could be found invalid or unenforceable if challenged in court.
- Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Risks Related to Our Business and Strategy

- We will need to continue to develop and expand, and if we fail to manage such development and expansion effectively, our expenses could increase more than expected, our revenue may not increase sufficiently to generate sustainable profits and we may be unable to successfully execute on our growth initiatives, business strategies or operating plans.
- Our ability to identify, engage with, and retain Plenity patients is essential to our ability to grow and sustain our sales.
- We rely on a limited number of channels for the distribution of Plenity, with a few qualified distributors currently accounting for substantially all of our revenue. The loss of one or more of such qualified distributors would materially harm our business.
- We depend on collaborations with third parties for the commercialization of Plenity in certain markets. If our third-party partners do not launch and successfully commercialize Plenity in key markets before our competitors offer products for the same or similar uses, we may not be able to fully capitalize on the market potential of Plenity.
- Our future success depends on our ability to retain our senior executive officers, and to attract and keep senior management and key scientific and commercial personnel.
- We may not be successful in our efforts to identify or discover additional product candidates.
- We face potential product liability exposure and, if claims are brought against us, we may incur substantial liability.
- If we do not continually enhance our brand recognition, increase distribution of Plenity, attract new patients and introduce new and innovative products, either on a timely basis or at all, our business may suffer.
- Our international operations for the supply chain of Plenity pose certain political, legal and compliance, operational, regulatory, economic and other risks to our business that may be different from or more significant than risks associated with our U.S. operations.
- Competition from other weight management and wellness industry participants or the development of more effective or more favorably perceived weight management methods could result in decreased demand for Plenity.

Risks Related to Ownership of Our Common Stock

- The price of our Common Stock has been, and may continue to be, volatile, and you could lose all or part of your investment.
- In November 2022, we received letters from the NYSE indicating that we were not in compliance with the continued listing standard set forth in Rule 802.01C of the NYSE Listed Company Manual.
- Securities of many companies formed through a merger or other business combinations with a SPAC, such as ours, have experienced a material decline in price relative to the share price of the SPAC prior to the Business Combination.

Risks Related to Financial Position and Financing Needs

We are a commercial stage biotherapeutics company, but to date we have generated limited product sales. We have incurred significant operating losses since our inception and anticipate that we will continue to incur continued losses for the next several years.

We are a commercial stage biotherapeutics company and to date we have funded our operations through proceeds from collaborations, the issuance of common stock and convertible preferred stock, the issuance of convertible and non-convertible debt and non-dilutive grants received from government agencies. We have incurred losses in each year since our inception, other than fiscal year 2013. Our net losses were $55.8 million and $93.3 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $298.1 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. We expect to incur increasing levels of operating losses over at least the next several years. We expect to continue to incur significant sales and marketing expenses and additional costs associated with operating as a public company. Because of the numerous risks and uncertainties associated with commercializing Plenity and developing any future product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate product sales. To date, we have generated limited product sales of Plenity, and we do not know when or if we will generate meaningful product sales from Plenity. Our ability to generate product sales depends on a number of factors, including, but not limited to, our ability to:

- commercialize Plenity by developing a sales force or entering into collaborations with third parties;
- achieve market acceptance of Plenity in the medical community and with patients, many of whom could be required to pay out-of-pocket for Plenity; and
- supplement our clinical scale to meet demand in a facility owned or leased by us or by a strategic collaboration partner or third-party manufacturer.

We expect to incur significant sales and marketing costs as we commercialize Plenity and we may not achieve profitability soon after generating product sales, if ever, and we may be unable to continue operations without continued funding. Failure to successfully commercialize Plenity would materially harm our business, financial condition and results of operations.

We may be unable to accurately forecast revenue and appropriately plan our expenses in the future.

We base our current and future expense levels on our operating forecasts and estimates of future income. Income and results of operations are difficult to forecast because they generally depend on our ability to fully commercialize Plenity, including our ability to quickly and efficiently scale production thereof, which remains uncertain. Additionally, our business is affected by general economic and business conditions around the world, including the impact of the COVID-19 pandemic. A softening in income, whether caused by changes in consumer preferences or a weakening in global economies, may result in decreased demand for Plenity or our ability to generate adequate supply of Plenity, which in turn would negatively impact our revenue levels and make it increasingly difficult to achieve and maintain profitability. If so, and we are unable to adjust our spending in a timely manner to compensate for any unexpected shortfall in the commercialization of Plenity, we could experience lower net income or greater net loss in a given quarter than expected.

In order to support our business, we will need to incur additional indebtedness or seek capital through new equity or debt financings, which sources of additional indebtedness or capital have become increasingly difficult to secure and may not be available on acceptable terms, if at all, and the failure to obtain this additional funding when needed may force us to delay, limit or terminate our product development efforts or other operations.

We are currently commercializing Plenity. Manufacturing and marketing our hydrogel technology is expensive and, accordingly, we expect our manufacturing and marketing expenses will increase substantially in connection with any ongoing commercialization activities. However, we will require additional capital to fund our growth and operating needs, including our ongoing commercialization activities. We will also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for Plenity or otherwise expand more rapidly than we presently anticipate.

As of December 31, 2022, our cash and cash equivalents were $24.8 million. Upon the close of the Business Combination in January 2022, we received approximately $105 million of gross proceeds to fund our operations. Due to a significant number of redemptions associated with the Business Combination, we determined to seek additional funds sooner than originally planned, through public or private equity or debt financings, government or other third party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these sources. For example, on July 25, 2022 and August 4, 2022, we issued the 2022 Promissory Notes in the aggregate principal amount of $25.0 million to CMS, PureTech and SSD2 (together, the "Promissory Note Investors") for an aggregate cash purchase price of $25.0 million. In addition, on August 11, 2022, we established a Committed Equity Facility pursuant to which we will have the right, but not the obligation, to sell to B. Riley up to the lesser of (i) $50,000,000 of newly issued shares of Common Stock, and (ii) 14,506,475 shares of our Common Stock from time to time, at our sole discretion.

However, we will require additional capital to continue to commercialize Plenity and to develop and commercialize any future product candidates. There is a substantial correlation between our sales of Plenity and our expenditure on marketing. For example, in January 2022, we launched a broad awareness media campaign for Plenity that resulted in significant increases in our web traffic and in the number of individuals seeking new Plenity prescriptions compared to previous months. Our ability to expand our customer base through marketing efforts such as our January 2022 media campaign, and generate related revenue, is dependent upon our ability to successfully raise the capital to fund such efforts. Our failure to obtain additional funding may force us to delay, limit or terminate our marketing efforts, which may negatively impact our ability to attract enough customers to operate profitably. If we cannot operate profitably, we may have to suspend or cease operations which could cause our Common Stock to lose value.

Even if we ultimately obtain sufficient funds for our current or future operating plans, we may nevertheless seek additional capital through debt or equity financings if market conditions are favorable or if we have specific strategic considerations. Such financing is increasingly difficult to secure and there can be no assurance that such debt or equity financings will be available on acceptable terms or will be able to be completed at all. If we are unable to obtain additional funding on a timely basis, or at all, we may be required to significantly curtail, delay or discontinue our research or development programs or the commercialization of Plenity (including limitations on marketing efforts) or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

If we are not successful in implementing an alternative business plan and/or raising additional capital in a timely manner, we may have insufficient cash and liquidity to pay operating expenses and other obligations. Any such event would have a material adverse effect on our business and financial condition.

We implemented an alternative business plan, prioritizing short-term working capital needs such as investments in raw materials and finished goods as well as investments in sales and marketing, and delaying certain long-term capital expenditures in commercial infrastructure and certain research and development expenses. We reduced and optimized investments in sales and marketing, prioritizing investments in high return and high exposure mediums. We have sought out alternative commercial arrangements or geographic distribution partnerships to finance certain investments in sales and marketing associated with the full commercial launch of Plenity. We expect these actions will provide us with sufficient liquidity to manage short-term risk and uncertainty and (i) enable us to execute our alternative business plan, (ii) afford us time to access financing alternatives to provide for long-term liquidity and (iii) enable us to fund the continued commercialization of Plenity. These changes to the execution of our business plan may impact the growth of Plenity sales and the pace of acquisition and retention of consumers. We may need to raise additional capital to fund our operations and our alternative business plan. There can be no assurance that we will be successful in obtaining capital sufficient to meet our operating needs on terms or a timeframe acceptable to us or at all. Further, in the event that market conditions preclude our ability to consummate such a transaction, we may be required to evaluate additional alternatives in restructuring our business and our capital structure.

We believe our current cash and cash equivalents will not be sufficient to fund our business for the next twelve months from the date of the unaudited consolidated financial statements included elsewhere in this Form 10-K, raising substantial doubt about our ability to continue as a going concern.

As of December 31, 2022, our cash and cash equivalents was $24.8 million. Based on our current operating plan, considering the aggregate proceeds from the post-period issuance of the 2022 Promissory Notes and the post-period CMS amendment, we expect that our existing cash and cash equivalents will only be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2023 and not at least twelve months beyond the date of issuance of the unaudited consolidated financial statements included elsewhere in this Form 10-K without generating positive cash flows through increased revenue and by raising additional capital from outside sources (including, for example, our Committed Equity Facility). In addition, we anticipate that this extension of our cash runway into the second quarter of 2023 will only be achievable with a significant reduction of discretionary spending from prior levels, particularly with respect to our discretionary sales and marketing activities and manufacturing and supply chain functions. In addition, our current operating plan is based on current assumptions that may prove to be wrong, and we could use

our available capital resources sooner than is currently expected. As stated above, if we are unable to obtain additional funding on a timely basis, or at all, we may be required to significantly curtail, delay or discontinue our research or development programs or the commercialization of Plenity (including our marketing efforts) or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code, which could materially affect our business, financial condition and results of operations. There can be no assurance that we will be able to continue as a going concern.

Raising additional funding in the future may cause dilution to our stockholders, restrict our operations or require us to relinquish rights.

We may seek additional capital through a combination of private and public equity and debt offerings, government or other third party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these sources. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest in us will be diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect your rights as a stockholder. For example, on August 11, 2022, we established our Committed Equity Facility with B. Riley, which provides for the sale of Common Stock by us at a discount to the market price contemporaneous with the time of the sale, and if and when we sell shares of Common Stock to B. Riley under the program, after B. Riley has acquired such shares, it may resell all, some, or none of those shares at any time or from time to time in its discretion. Therefore, sales to B. Riley pursuant to our Committed Equity Facility would result in substantial dilution to our existing stockholders and the resale of such shares by B. Riley could negatively impact the market price for our Common Stock. We also may be unable to sell shares of our Common Stock pursuant to the Committed Equity Facility if the market price for our Common Stock remains below $1.00. In addition, upon a payment default under any of our 2022 Promissory Notes we issued on July 25, 2022 and August 4, 2022 that is not cured after five days, (i) we will be required to issue certain warrants to the holder of such note, which the holder may then exercise for shares of our Common Stock and (ii) the holder of such 2022 Promissory Note will also have the option to convert the outstanding principal and accrued interest under such note into a number of shares of our Common Stock. Further debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to Plenity, our intellectual property or future revenue streams or grant licenses on terms that are not favorable to us.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. Although we are not a borrower or party to any such instruments with SVB, Signature or any other financial institution currently in receivership, if any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis. For example, as of March 10, 2023, we had substantially all of our cash and cash equivalents held in deposit accounts at SVB, in which case our access to our cash and cash equivalents in amounts adequate to finance our operations could have been significantly impaired by SVB's liquidity constraints and failure.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities

held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and/or delays, inability or reductions in the company's ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on the Company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer or supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to us and may have a material adverse impact on our business.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

We had federal and state net operating loss carryforwards of $254.7 million (federal) and $221.2 million (state), as of December 31, 2022. Our federal net operating loss carryforwards begin to expire in 2027, and our state net operating loss carryforwards began to

expire in 2030. Under Section 382 of the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and research and development tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and research and development tax credit carryforwards before they expire. These limitations, whether as the result of the Business Combination, the PIPE Financing, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us hereafter, could have a material adverse effect on the amount of net operating losses we can utilize to offset future taxable income.

Risks Related to Product Development, Regulatory Approval and Commercialization

We are dependent on the success of our hydrogel technology for Plenity, which is currently our only marketed and FDA-authorized product.

Plenity is currently our only marketed FDA *de novo* authorized product and our business depends on the successful commercialization of Plenity. We may never be able to achieve widespread market acceptance of Plenity or, if we do, be able to develop additional indications for Plenity, which will require substantial additional clinical development, testing and regulatory approval before we are permitted to commercialize those indications. The manufacturing and marketing of Plenity is subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to market Plenity. Because our business is almost entirely dependent upon Plenity and our underlying hydrogel technology, any setback in our pursuit of commercialization of Plenity would have a material adverse effect on our business and prospects.

Plenity may cause undesirable side effects that could result in significant negative consequences, including product liability or other litigation, that may be costly to us and/or adversely impact the commercial success of Plenity.

Undesirable side effects caused by Plenity could cause us, the FDA or European regulatory authorities to interrupt, delay or halt the continued commercialization of Plenity and could result in more restrictive labeling, or withdrawal or limitations on Plenity's marketing approval. To date, the main adverse events in patients taking Plenity have been bloating, flatulence, abdominal pain and diarrhea. However, there have been no serious adverse events attributed to Plenity and the difference in adverse events between Plenity and placebo has been negligible. If we or others identify other undesirable side effects caused by Plenity, a number of potentially significant consequences could result, including:

- the FDA or European notified bodies may withdraw or limit their marketing approval of the product;
- the FDA or European notified bodies may require the addition of labeling statements, such as a black box warning or a contraindication;
- we may be required to change the way the product is distributed or administered, conduct additional clinical trials or change the labeling of the product;
- we may decide to remove the products from the marketplace;
- we could be sued and held liable for injury caused to individuals using our product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of Plenity and could substantially increase the costs of commercializing the product and/or significantly impact our ability to successfully commercialize and generate product sales.

The broad prescription pharmaceutical and medical device market for overweight and obesity is strictly regulated.

Even though we obtained the required regulatory approval in the United States, our ability to generate product sales is dependent on our ability to market and sell Plenity, which depends upon the awareness and acceptance of Plenity among the medical community, including physicians and patients. If Plenity does not achieve an adequate level of acceptance by patients and physicians, we will not generate sufficient product sales of Plenity to become or remain profitable. Our efforts to educate the medical community about the benefits of Plenity may require significant resources and may never be successful.

We are, and will continue to be, subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

We are, and will continue to be, subject to ongoing FDA requirements and continued regulatory oversight and review, including routine inspections by the FDA of our manufacturing facilities and compliance with requirements such as the QSR, which establishes extensive requirements for quality assurance and control as well as manufacturing procedures; requirements pertaining to the registration of our manufacturing facilities and the listing of Plenity with the FDA; continued complaint, adverse event and malfunction reporting; corrections and removals reporting; and labeling and promotional requirements. The promotional claims we are, and will continue to be, able to make for Plenity are limited to the approved indications for use. We may also be subject to additional FDA post-marketing requirements. If we are not able to maintain regulatory compliance, we may not be permitted to market Plenity and/or may be subject to enforcement by the FDA such as the issuance of warning or untitled letters, the imposition of fines, injunctions, and civil penalties; the recall or seizure of products; the imposition of operating restrictions; and the institution of criminal prosecution. In addition, we will be subject to similar regulatory regimes in Europe for Plenity. Adverse EU Competent Authority or FDA action in any of these areas could significantly increase our expenses and limit our product sales and profitability.

The FDA and other regulatory authorities actively enforce the laws and regulations pertaining to the advertising and promotion of healthcare products. If we are found to have improperly promoted off-label uses, including for the use of an unapproved indication or in an unapproved age group or dosage, we may become subject to significant liability and corresponding litigation.

The FDA and European regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as Plenity. In particular, a medical device may not be promoted for uses that are not approved by the FDA or other regulatory authorities as reflected in the product's approved labeling. For example, we are not allowed to make claims for Plenity pertaining to diabetes management or glycemic control in prediabetic and type 2 diabetic patients without approval of specific labeling regarding such use. Even though we received marketing approval for Plenity to aid in weight management in overweight and obese adults with a body mass index (kg/m2), or BMI, of 25 - 40, when used in conjunction with diet and exercise, physicians may nevertheless prescribe Plenity to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to enforcement action by the FDA, including warning or untitled letters. In addition, the federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of Plenity, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Healthcare laws and regulations expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings, and our direct marketing strategy could enhance such exposure.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of Plenity. Any arrangements with third party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute Plenity. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties.
- The federal False Claims Act imposes criminal and civil penalties, including those from civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery.
- The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created

new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

- The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- The federal transparency requirements, sometimes referred to as the "Sunshine Act," under the Patient Protection and Affordable Care Act, require manufacturers of drugs, medical devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers. Some state laws require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring device manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing, with the reported information to be made publicly available on a searchable website.
- Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including current or future activities to be conducted by our or a collaborator's sales team, were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Plenity is currently regulated as a medical device by the FDA and may become subject to similar or other therapeutic regulatory requirements outside the United States.

Plenity is currently regulated by the FDA as a medical device and may become subject to similar or other therapeutic regulatory requirements outside of the United States. We expect to expand the sales of Plenity internationally, and as we do so we will also become subject to similar regulations by foreign governments. Government regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, storage, and distribution;
- premarketing clearance or approval or *de novo* authorization;
- record keeping;
- product marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths, serious injuries and product malfunctions, recalls, corrections and removals.

Any delay or failure to obtain necessary regulatory approvals, authorizations, or clearances for new product offerings, if any, could have a material adverse effect on our business, financial condition and results of operations. Material modifications to the intended use or technological characteristics of Plenity may also require new 510(k) clearances, premarket approvals, or *de novo* authorizations prior to implementing the modifications, or require us to recall or cease marketing Plenity until these clearances, approvals or

authorizations are obtained. For example, in January 2023, we submitted a 510(k), or premarket notification, to the FDA to change Plenity's classification in the United States from prescription-only to OTC, and anticipate FDA's decision on our 510(k) submission by the third quarter of 2023. If the FDA does not clear our 510(k), we will not be able to offer Plenity to consumers OTC, which could negatively impact our business.

In addition, we are required to timely submit various reports with the FDA, including reports that Plenity may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business, financial condition and results of operations. Any corrective actions can be costly, time-consuming, and divert resources from other portions of our business. Furthermore, the submission of these reports could be used by competitors against us, which could harm our reputation.

The FDA and the FTC also regulate the advertising and promotion of Plenity and services to ensure that the claims we make are consistent with our marketing authorizations, that there is adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising are neither false nor misleading. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

Recently enacted and future legislation may increase the difficulty and cost for us to further commercialize Plenity and any other products we may develop in the future and decrease the prices we may obtain for our approved products.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our products, restrict or regulate post-approval activities, and affect our ability to profitably sell our approved products and any product candidates for which we obtain marketing approval.

In March 2010, the Patient Protection and Affordable Care Act, or ACA, was enacted into law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms.

Among the provisions of the ACA of importance to Plenity and other product candidates are the following:

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti- Kickback Statute, new government investigative powers, and enhanced penalties for non-compliance;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report financial arrangements with physicians and teaching hospitals; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to reform through legislation and executive orders by the previous U.S. presidential administration and to judicial challenges. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

Other legislative changes have also been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. In addition, the Inflation Reduction Act of 2022, or IRA, includes several healthcare cost containment and reduction provisions that may impact our business to varying degrees. The effects of the IRA on our business and the healthcare industry in general is not yet known.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our products that obtain marketing approval. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from our products and product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop future product candidates. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product and product candidates, if approved;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the amount of taxes that we are required to pay; and
- the availability of capital.

We are responsible for manufacturing Plenity and currently have a validated and active commercial scale manufacturing facility that we are currently expanding, a fully functional pilot manufacturing site that can be quickly activated and land owned and zoned for commercial capacity expansion. We will continue to invest in manufacturing capacity at these sites and possibly build additional manufacturing sites to meet increased demand as Plenity is launched through new channels or in new markets. Our inability to produce an adequate supply of Plenity, due to the loss of these facilities or other future facilities or any material limitation of production at these facilities, could materially and adversely impact the commercial growth and success of Plenity and, consequently, could cause our revenue, earnings or reputation to suffer.

We have developed proprietary processes and manufacturing technologies for the production of Plenity. Our subsidiary, Gelesis S.r.l., operates manufacturing and research and development facilities in southern Italy that produce Plenity. These facilities are currently our sole supplier of Plenity and while we currently plan to expand the output of this facility in 2023 to meet the near term demands associated with the commercialization of Plenity there are no assurances that we will be able to do so successfully or at all.

Any performance failure by us could delay or otherwise adversely affect the commercialization of Plenity and we may encounter difficulties involving the production yields, regulatory compliance, lot release, quality control and quality assurance, as well as shortages of qualified personnel. Moreover, the ability to manufacture and supply Plenity adequately and in a timely manner is dependent on the uninterrupted and efficient operation of Gelesis S.r.l., which may be impacted by many manufacturing variables, including, but not limited to:

- availability of raw materials from suppliers;
- contamination of raw materials and components used in the manufacturing process;
- capacity of our facilities or those of our contract manufacturers, if any;
- the ability to adjust to changes in actual or anticipated use of the facility, including with respect to having sufficient capacity and a sufficient number of qualified personnel;
- facility contamination by microorganisms or viruses or cross contamination;
- compliance with regulatory requirements, including inspectional notices of violation and warning letters;

- changes in actual or forecasted demand;
- timing and number of production runs;
- production success rates; and
- timing and outcome of product quality testing.

In addition, we may encounter delays and problems in manufacturing Plenity for a variety of reasons, including accidents during operations, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental unrest or changes, social unrest, epidemics and pandemics, intentional misconduct or other factors inherent in operating complex manufacturing facilities. We may not be able to operate our manufacturing facility in a cost-effective manner or in a time frame that is consistent with manufacturing needs. If we cease or interrupt production or if other third parties fail to supply materials, products or services to us for any reason, such interruption could delay the commercial supply of Plenity, with the potential for additional costs and lost product sales. If this were to occur, we may also need to seek alternative means to fulfill our manufacturing needs. If we encounter unexpected failures or difficulties in our manufacturing process or require amounts of Plenity in excess of our current estimates we may be unable to manufacture sufficient supplies to support its commercialization, which will adversely impact the growth and success of Plenity and, consequently, could cause our revenue, earnings or reputation to suffer.

Furthermore, we will also be subject to ongoing periodic inspection, which may be unannounced, by the FDA, corresponding state authorities and European regulatory authorities to ensure strict compliance with QSR and other applicable government regulations and corresponding foreign standards. If we fail to maintain compliance or otherwise experience setbacks, we could be subject to enforcement action, including warning or untitled letters or civil or criminal penalties, the production of Plenity could be interrupted or suspended, or Plenity could be recalled or withdrawn, resulting in delays, additional costs and potentially lost product sales.

There is no guarantee that we will be able to successfully commercialize Plenity through the channels or in the markets we are targeting or at all.

The commercial success of Plenity depends upon the awareness and acceptance of Plenity among the medical community, including physicians and patients. Market acceptance of Plenity depends on a number of factors, including, among others:

- Plenity's demonstrated ability to aid in weight management in overweight and obese patients;
- the perceived advantages and disadvantages of Plenity over existing products and other competitive treatments and technologies for weight management in overweight and obese patients;
- the prevalence and severity of any adverse side effects associated with Plenity, such as bloating, flatulence, abdominal pain and diarrhea;
- limitations or warnings contained in the labeling approved for Plenity by the FDA or certain European notified bodies;
- availability of alternative treatments, including a number of competitive obesity therapies already approved or expected to be commercially launched in the near future;
- the extent to which physicians prescribe Plenity;
- the willingness of the target patient population to try new therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies; and
- the willingness of patients to pay out-of-pocket in the absence of third party reimbursement.

If Plenity does not achieve an adequate level of acceptance by patients and physicians, we will not generate sufficient product sales of Plenity to become or remain profitable. Our efforts to educate the medical community about the benefits of Plenity may require significant resources and may never be successful.

The telehealth market is immature and volatile, and if it does not develop, if it develops more slowly than we expect, or if it encounters negative publicity, our ability to fully commercialize Plenity and grow our business will be harmed.

Our ability to fully commercialize Plenity and grow our business will depend, to a certain extent, upon the willingness of patients to use, and extent of their utilization of, telehealth services. The telehealth market is relatively new and unproven, and it is uncertain whether it will achieve and sustain high levels of demand, consumer acceptance and market adoption. The COVID-19 pandemic has increased utilization of telehealth services, but it is uncertain whether such increase in demand will continue post-pandemic. Negative publicity concerning the telehealth market as a whole could limit market acceptance of, or ability to generate sales of, Plenity. If patients do not engage with Plenity through telehealth services then our ability to access potential patients and, accordingly, our market, may be limited, may develop more slowly than we expect, or may not develop at all. Similarly, individual and healthcare industry concerns or negative publicity regarding patient confidentiality and privacy in the context of telehealth could limit the use of telehealth services to access Plenity. If any of these events occurs, it could have a material adverse effect on our business, financial condition and results of operations.

Our ability to market and sell Plenity through telehealth services in a particular jurisdiction is directly dependent on the applicable laws that govern remote healthcare and the practice of medicine and healthcare delivery in general in such jurisdiction, which are subject to changing political, regulatory and other influences that may restrict our use of telehealth services or otherwise negatively impact our business model and growth.

The ability of our qualified distributors to market and sell Plenity through telehealth services in a particular jurisdiction is directly dependent upon the applicable laws in such jurisdiction that govern remote healthcare and the practice of medicine and healthcare delivery in general in such jurisdictions, which are subject to changing political, regulatory and other influences. Some state medical boards have established rules or interpreted existing rules in a manner that may limit or restrict the ability of our qualified distributors to use telehealth services in connection with providing patients with access to Plenity or otherwise negatively impact our business model and growth.

Telehealth offers patients the ability to see a licensed medical professional for advice, diagnosis and treatment of routine health conditions on a remote basis, which has been particularly important during the COVID-19 pandemic. Due to the nature of this service and the provision of medical care and treatment by licensed medical professionals, certain of our qualified distributors and their physicians and healthcare professionals who prescribe our products via telehealth are and may in the future be subject to complaints, inquiries and compliance orders by national and state medical boards. Such complaints, inquiries or compliance orders may result in disciplinary actions taken by these medical boards against the licensed physicians who provide Plenity through these telehealth services, which could include suspension, restriction or revocation of the physician's medical license, probation, required continuing medical education courses, monetary fines, administrative actions and other conditions and would, in turn, limit the distribution of Plenity and slow our commercialization efforts.

Due to the uncertain regulatory environment, certain states may determine that our qualified distributors and their affiliated physicians or healthcare professionals are in violation of their laws and regulations or such laws and regulations may change. In the event that we must remedy such violations, we may be required to modify how we utilize telehealth services, if at all, in connection with the distribution of Plenity in such states in a manner that undermines our business, we may become subject to fines or other penalties or, if we determine that the requirements to operate in compliance in such states are overly burdensome, we may elect to terminate our operations in such states. In each case, our revenue may decline and our business, financial condition and results of operations could be materially adversely affected.

In order to sell, market and distribute Plenity, we may enter into additional strategic collaborations with third parties. We have limited experience with such collaborations and if we have problems establishing these relationships, the commercialization of Plenity could be impaired.

We are continually evaluating changing consumer preferences and the competitive environment of the weight management industry and seeking out opportunities to improve our performance through the implementation of selected strategic collaborations. The goal of these efforts is to develop and implement a comprehensive and competitive business strategy that addresses those changes and drives the sale and distribution of Plenity. We may not be able to successfully implement our strategic collaborations and realize the intended business opportunities, growth prospects, including new business channels, and competitive advantages. Our efforts to capitalize on business opportunities may not bring the intended results. Assumptions underlying expected financial results or consumer demand and receptivity may not be met or economic conditions may deteriorate. We also may be unable to attract and retain highly qualified and skilled personnel to implement our strategic collaborations and we have limited experience implementing such arrangements with third parties. If we have problems establishing these relationships or executing thereunder, the commercialization of Plenity could be impaired.

Successful commercialization of Plenity is dependent on the willingness of the ultimate patient to pay out-of-pocket. If there is not sufficient patient demand for Plenity, our financial results and future prospects will be harmed.

We cannot be certain that third party reimbursement will be available for Plenity, and, if reimbursement is available, the amount of any such reimbursement. As a result, we expect that our success will be dependent on the willingness of patients to pay out-of-pocket for Plenity. The decision by a patient to elect to undergo treatment with Plenity may be influenced by a number of factors, such as:

- the success of any sales and marketing programs, including direct-to-consumer marketing efforts, that we, or any third parties we engage, undertake, and as to which we have limited experience;
- the extent to which physicians prescribe Plenity for their patients;
- the extent to which Plenity satisfies patient expectations;
- the cost, safety, and effectiveness of Plenity as compared to other treatments; and
- general consumer confidence, which may be impacted by economic and political conditions.

Our financial performance will be materially harmed if we cannot generate significant patient demand for Plenity.

Competing products and technologies could emerge, including pharmaceuticals, devices and surgical procedures, that adversely affect our opportunity to generate sales of Plenity and achieve profitability.

The biotechnology, pharmaceutical and medical device industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Competitors may invest heavily to quickly discover and develop products that could make Plenity obsolete or economically disadvantageous. Competitors may also choose to develop a product that is substantially equivalent to Plenity and obtain clearance through the FDA's 510(k) clearance process, taking advantage of our investment and work. A new product that competes with Plenity may need to demonstrate that it is substantially equivalent to Plenity or that it has compelling advantages in efficacy, convenience, tolerability and safety to be commercially successful, which if demonstrated, could adversely affect our sales of Plenity and, therefore, our profitability. Competing products, whether substantially equivalent or not, may also be sold at lower prices. This and other competitive factors could force us to lower prices or could result in reduced sales. In addition, products developed by others could emerge as competitors to Plenity. If we are not able to compete effectively against our competitors, our financial condition and operations will suffer.

Our competitors in the obesity market include drugs that are FDA-approved and currently marketed for the treatment of obesity. Plenity primarily competes with orlistat, phentermine/topiramate and naltrexone/ bupropion, three orally administered, marketed pharmaceutical products in the United States for the treatment of obesity, and several older products, indicated for short-term administration, including phentermine, phendimetrazine, benzphetamine and diethylpropion. Orlistat is marketed in the United States by Roche Group under the brand name Xenical and over-the-counter under the brand name alli, at half the prescribed dose, by GlaxoSmithKline. Vivus, Inc. also has a combination product, phentermine/ topiramate, which is marketed under the trade name Qsymia, Further, Orexigen Therapeutics, Inc. received FDA approval of naltrexone/bupropion which is marketed under the brand name Contrave in the United States and has also received marketing approval under the name Mysimba in the European Union. Plenity also competes with injectable pharmaceutical obesity therapies, including Saxenda and Wegovy marketed by Novo Nordisk. In addition, other approaches which utilize various implantable devices or surgical tools marketed by Apollo EndoSurgery, Inc., Obalon Therapeutics, Inc., Aspire Bariatrics, Inc., Scientific Intake Limited Co., and BioEnterics Corporation.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we have. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitors also may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Risks Related to Intellectual Property Rights

If we are unable to adequately protect our proprietary technology or maintain issued patents that are sufficient to protect Plenity, or if competitors are able to market competitive products without infringing our protected intellectual property rights, others could compete against us in ways that would have a material adverse impact on our business, results of operations, financial condition and prospects.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual

property and proprietary technology, competitors may be able to use our technologies without infringing on our intellectual property rights and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability.

As of December 31, 2022, we own nine families of patents and patent applications relating to our hydrogel technology, two of which are directed to methods of treating obesity and reducing caloric intake using certain hydrogels, the hydrogel composition in Plenity and methods of producing hydrogels. The issued U.S. patents in these two families have expiration dates or projected expiration dates ranging from 2028 to 2033. We cannot provide any assurances that competitors will not practice the claims in our issued patents, or that claims in our issued patents are valid. Further, we cannot provide any assurances that the scope of the claims is sufficient to protect Plenity or its uses or that competitors will practice the claims. In Europe, there are additional issued patents directed to the hydrogel in Plenity, its production and uses of certain hydrogels to treat obesity and reduce caloric intake. In one of the seven other patent families, we have pending applications directed to treating overweight and obesity with certain hydrogels that are projected to expire in 2035.

We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect Plenity, that they will be sufficient to prevent competitors from marketing competitive products or that any indications obtained for Plenity, now or in the future, will be protected by any issued or future claim. Other parties have developed technologies that may be related or competitive to our approach and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. The patent positions of biotechnology, pharmaceutical and medical device companies, including our patent position, involve complex legal and factual questions and, therefore, the issuance, scope, validity, and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patent law is continually evolving and rapidly changing, creating uncertainty and risk. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented or it may be determined that competitive products do not infringe upon our rights. U.S. patents and patent applications may also be subject to interference proceedings, ex parte reexamination, inter partes review proceedings, post-grant review proceedings and challenges in district court. Patents may also be subjected to opposition, post-grant review, or comparable proceedings lodged in various foreign, both national and regional, patent offices.

These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize Plenity.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability, and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar or equivalent products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees. We also may encounter significant problems in protecting our proprietary rights in foreign countries. If these developments were to occur, they could have a material adverse effect on our sales.

Our ability to enforce our patent rights depends on the scope of our claims and our ability to detect infringement. It is difficult to detect infringers who do not advertise the components of their products or how they are made. Moreover, it may be difficult or impossible to obtain evidence of infringement in a potential competitor's product or methods of production. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Third parties may also assert claims that they do not practice our patents and seek a determination of non-infringement.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering Plenity are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect Plenity;

- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize Plenity, before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be infringed;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

We also rely upon unpatented trade secrets, unpatented know-how, and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors, which could adversely affect our business, financial condition and results of operations.

We have licensed Plenity to third party partners (e.g. for launch in Greater China, including Mainland China, Hong Kong, Macau, and Taiwan) and have also granted limited licenses to practice patent rights for noncommercial, research purposes. We may continue to out-license our intellectual property and may agree under certain circumstances to grant limited exclusive or non-exclusive commercial rights as well. There can be no guarantee that the third party's activities will not in any way overlap or interfere with the commercialization of Plenity. Additionally, there is always the possibility that we may become dependent on obtaining access to third party intellectual property in connection with the commercialization of Plenity or for other new product candidates in the future.

We have acquired certain patent rights that cover Plenity and these rights impose various obligations on us, including a requirement to make certain milestone and royalty payments and to prosecute and maintain the patent rights. We have also granted a non-exclusive license to practice the patent rights for noncommercial, research purposes, and we have agreed under certain circumstances to grant an additional non-blocking license for the development and commercialization of certain drug delivery products that do not include any composition of matter that is claimed by the patent rights, exclusive of products relating to obesity, weight loss, diabetes, metabolic diseases, GI disorders, laxatives and liquid removal. While we believe that the scope of any non-blocking license will be clearly distinct from our field of interest, there can be no guarantee that a disagreement will not arise over a particular product area, or that such a disagreement could not materially and adversely impact our business. In addition, we have also granted an exclusive, transferable, sublicensable, and royalty-bearing license of our intellectual property to develop, import, register, manufacture, and commercialize Plenity in Greater China (including Mainland China, Hong Kong, Macau, and Taiwan), Singapore and United Arab Emirates.

Additionally, under these agreements, such third parties have agreed to assign to us certain future technology relating to food products that they develop during the term of the agreements, as well as other improvements to our existing intellectual property rights that result from activities they perform under the agreements. There can be no guarantee, however, such third parties will not attempt to act contrary to such obligations or that, if they do, we would succeed in a legal action to stop them from doing so.

We may be required to enter into additional license(s) to use third party intellectual property that we find necessary or useful to our business, or because that third party owner asserts we are infringing on such third party intellectual property. In such a case, even if we are successful in obtaining terms that are commercially reasonable, such a future licensor might also allege that we have breached our license agreement and may accordingly seek to terminate our license with them or may insist on the right to terminate such a license at will. If successful, any such termination could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects.

We may infringe the intellectual property rights of others, which may prevent or delay our development efforts or stop us from commercializing or increase the costs of commercializing Plenity.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties.

The medical device, pharmaceutical and biotechnology industries are characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that Plenity or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing another party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing Plenity or our other product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease selling or otherwise commercializing Plenity;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign or rename Plenity to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. For example, each of our patents and patent applications names one or more inventors affiliated with other institutions, any of whom may assert an ownership claim. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is

not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our Common Stock.

Issued patents covering Plenity could be found invalid or unenforceable if challenged in court.

If we initiated legal proceedings against a third party to enforce a patent covering our product candidate, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness, indefiniteness or non-enablement.

Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they do not cover Plenity or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on Plenity. Such a loss of patent protection would have a material adverse impact on our business.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

We do not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on Plenity and any other product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and we did not pursue intellectual property rights in some countries outside the United States.

In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as in other jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all jurisdictions, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is limited. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals and medical devices, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has implemented the America Invents Act of 2011, which was wide-ranging patent reform legislation. Further, the Federal Circuit and the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, such as with respect to patent claims using "consisting essentially of" transitional language. In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents or future patents.

We may be subject to damages resulting from claims that we, our employees, consultants or third parties we engage to manufacture our products have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at pharmaceutical companies and other medical device companies, including our potential competitors, in some cases until recently. We may be subject to claims that we, our employees, consultants or third parties have inadvertently or otherwise used or disclosed alleged trade secrets or proprietary information of these former employers or competitors. In addition, we may be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction for our management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with third parties. A loss of key personnel or their work product could have an adverse effect on our business, results of operations and financial condition.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- we or our licensors or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;
- we or our licensors or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;

- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- countries other than the U.S. may, under certain circumstances, force us or our licensors to grant a license under our patents to a competitor, thus allowing the competitor to compete with us in that jurisdiction or forcing us to lower the price of our product in that jurisdiction;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not successfully commercialize the product candidates, if approved, before our relevant patents expire; and
- we may not develop additional proprietary technologies for which we can obtain patent protection.

Risks Related to Our Business and Strategy

We will need to continue to develop and expand, and if we fail to manage such development and expansion effectively, our expenses could increase more than expected, our revenue may not increase sufficiently to generate sustainable profits and we may be unable to successfully execute on our growth initiatives, business strategies or operating plans.

As of December 31, 2022, we had 93 full-time employees and 7 consultants and we expect to continue to increase the number of our administrative employees. We also plan to continue to expand the scope of our operations including the development of a commercial-scale manufacturing line and hiring manufacturing staff. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage such development and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the commercialization of Plenity, and we may not be able to sufficiently increase our revenue to generate sustainable profits. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our product sales could be reduced, and we may not be able to successfully execute on our growth initiatives, business strategies or operating plans. Our future financial performance and our ability to commercialize Plenity and compete effectively will depend in part on our ability to effectively manage the future development and expansion of our company.

Our estimated addressable market is subject to inherent challenges and uncertainties. If we have overestimated the size of our addressable market generally or markets in which we intend to offer Plenity, our future growth opportunities may be limited.

Data regarding the size and potential growth of the addressable market for weight management and weight loss solutions, generally, and the size of the target market for Plenity, specifically in the United States, is based upon, in part, internal estimates, forecasts and information obtained from independent trade associations, industry publications and surveys and other independent sources, proprietary research studies and management's knowledge of the industry, and is subject to significant uncertainty and is based on assumptions that may not prove accurate. While these estimates are made in good faith and are based on assumptions and estimates we believe to be reasonable, they may not be accurate and are subject to change. If we have overestimated the size of the addressable market for Plenity, including within the markets in which we intend to offer Plenity, our future growth opportunities may be limited.

Our ability to identify, engage with and retain Plenity patients is essential to our ability to grow and sustain our sales.

Sales of Plenity are our sole source of revenue, and our future growth depends upon our ability to identify, engage with, retain and grow our patient base and audience. To do so will require us to address changing consumer demands and developments in technology and improve Plenity, including by developing additional indications, while continuing to provide our distributors and patients with guidance and inspiring them on their weight management journeys by providing a product that provides meaningful results. We have invested and will continue to invest significant resources in these efforts, but there is no assurance that we will be able to successfully

maintain and increase our patient base or that we will be able to do so without taking steps such as reducing pricing or incurring manufacturing costs that would affect our revenues, margin and/or profitability.

We depend on collaborations with third parties for the commercialization of Plenity in certain markets. If our third-party partners do not launch and successfully commercialize Plenity in key markets before our competitors offer products for the same or similar uses, we may not be able to fully capitalize on the market potential of Plenity.

We have entered into agreements with third-party partners for the launch and commercialization of Plenity in certain markets. For example, in June 2020, we entered into a License, Collaboration and Supply Agreement with CMS Bridging DMCC, which was subsequently expanded and amended in August 2022, for CMS Bridging DMCC to develop, import, register, manufacture, and commercialize Plenity in Greater China and certain other territories. The launch and commercialization of Plenity by our third-party partners in certain markets may be subject to the receipt of regulatory approvals or the satisfaction of other conditions. Our ability to generate milestone and royalty payments from our agreements with our third-party partners will depend on our partners' abilities to obtain necessary approvals and otherwise successfully perform the functions assigned to them in these agreements. We cannot predict the success of our third-party partners. If competitors are able to successfully launch competitive products more rapidly than our partners are able to launch Plenity or if our third-party partners are not effective in commercializing Plenity, our potential milestone and royalty payments from sales of Plenity may be reduced.

We depend on a limited number of third-party suppliers, and the loss of any of these suppliers or their inability to provide us with an adequate supply of materials or distribution could harm our business.

We rely on a limited number of third-party suppliers to provide certain components for the hydrogel technology utilized in the manufacture of Plenity as well as related packaging for Plenity. The supply and price of these components are subject to market conditions and are influenced by many factors beyond our control, including pandemics (such as the COVID-19 pandemic) or other outbreaks of contagious diseases, weather patterns affecting component production, governmental programs and regulations, labor disruptions, and inflation. Although we strive to maintain relationships with suppliers with the objective of ensuring that we have adequate sources for the supply of such components and packaging materials, increases in demand for such items, both within our industry and in general, can result in shortages and higher costs. Our suppliers may not be able to meet our delivery schedules, we may lose a significant supplier, a supplier may not be able to meet performance and quality specifications and we may not be able to purchase such items at a competitive cost. Our freight costs may increase due to factors such as limited carrier availability, increased fuel costs, increased compliance costs associated with new or changing government regulations, pandemics (such as the COVID-19 pandemic) or other outbreaks of contagious diseases and inflation. Higher prices for natural gas, propane, electricity and fuel also may increase our component, production and delivery costs. The prices charged for Plenity may not reflect changes in our component, packaging material, freight, tariff and energy costs at the time they occur, or at all.

The loss of key supply sources, for any reason, our inability to obtain necessary quantities of components and packaging materials or changes in freight or energy costs may limit our ability to maintain existing margins and may have a material adverse effect on our business, financial condition, results of operations and cash flows. If we fail or are unable to hedge and prices subsequently increase, or if we institute a hedge and prices subsequently decrease, our costs may be greater than anticipated or greater than our competitors' costs, and our business, financial condition, results of operations and cash flows could be adversely affected.

We rely on a limited number of channels for the distribution of Plenity, with a few qualified distributors currently accounting for substantially all of our revenue. The loss of one or more of such qualified distributors would materially harm our business.

For each of the years ended December 31, 2022 and 2021, we relied on three customers or distributors for the distribution of Plenity accounting for 100% of our revenue. We also rely on our reputation and recommendations from key qualified distributors in order to promote Plenity to potential new patients. The loss of any of our key qualified distributors, or a failure of some of them to renew or expand their relationships with us, could have a significant impact on the growth rate of our revenue, reputation and our ability to obtain new users. In addition, mergers and acquisitions involving our qualified distributors could lead to cancellation or non-renewal of our contracts with those distributors or by the acquiring or combining companies, thereby reducing the number of our existing and potential distributors, which would materially harm our business.

If our existing qualified distributors do not continue or renew their contracts with us, renew at lower price levels or decline to purchase additional amounts of Plenity from us, it could have a material adverse effect on our business, financial condition and results of operations.

We expect to derive a significant portion of our revenue from renewal of existing qualified distributor contracts and sales of Plenity to existing distributors. As part of our growth strategy, for instance, we have recently focused on the distribution of Plenity through

telehealth services as well as using our sales force to drive sales of Plenity. As a result, increasing sales of Plenity is critical to our future business, revenue growth and results of operations.

Factors that may affect our ability to increase sales of Plenity include, but are not limited to, the following:

- the price, performance and safety of Plenity;
- the availability, price, performance and functionality of competing solutions;
- changes in healthcare laws, regulations, enforcement of such laws and regulations, or other trends; and
- the business environment of our qualified distributors.

We enter into exclusive supply and distribution agreements with our qualified distributors. Most of our distributors have no obligation to renew their contracts with us after the initial term expires. In addition, our distributors may negotiate terms less advantageous to us upon renewal, which may reduce our revenue from these distributors. Our future results of operations also depend, in part, on our ability to expand the number of our distributors. If our distributors fail to renew their contracts, renew their contracts upon less favorable terms or at lower fee levels or fail to purchase new products and services from us, our revenue may decline, or our future revenue growth may be constrained.

Our future success depends on our ability to retain our senior executive officers and to attract and keep senior management and key scientific and commercial personnel.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly Yishai Zohar, our Chief Executive Officer and President, as well as other employees and consultants. Although none of these individuals has informed us to date that he intends to retire or resign in the near future, the loss of services of any of these individuals or one or more of our other members of senior management could delay or prevent the successful commercialization of Plenity and the development of future product candidates.

Although we have not historically experienced significant difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology, pharmaceutical and medical device field is intense, and we face competition for the hiring of scientific and clinical personnel from other biotechnology and pharmaceutical companies, as well as universities and research institutions. In addition, the consultants and advisors, including scientific and clinical advisors, upon whom we rely to assist us in formulating our research development and commercialization strategy, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. In addition, we will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, if at all.

We may not be successful in our efforts to identify or discover additional product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize products using our proprietary hydrogel technology. Although Plenity is currently in the early stages of commercialization, our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and European regulatory authorities, provide accurate information to the FDA and applicable non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, as well as the Foreign Corrupt Practices Act, or FCPA, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course

of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We face potential product liability exposure and if claims are brought against us, we may incur substantial liability.

The sale of Plenity exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with Plenity. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend ourselves against them, we could incur substantial liabilities.

In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things:

- withdrawal of patients from our clinical trials;
- substantial monetary awards to patients or other claimants;
- decreased demand for Plenity or any future product candidates following marketing approval, if obtained;
- damage to our reputation and exposure to adverse publicity;
- increased FDA warnings on product labels;
- litigation costs;
- distraction of management's attention from our primary business;
- loss of sales; and
- the inability to successfully commercialize Plenity or any future product candidates, if approved.

Our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including if insurance coverage becomes increasingly expensive.

Significant judgments have been awarded in class action lawsuits based on drugs and medical devices that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our stock price to decline, and if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, business and prospects could be materially adversely affected.

If the weight management industry is subject to adverse publicity, our business could be harmed.

Unfavorable publicity regarding, for example, the weight management industry, the healthcare industry, litigation or regulatory activity, the actions of the entities included or otherwise involved in our platform, negative perceptions of Plenity, our hydrogel technology, pricing, our data privacy or data security practices, telehealth services or our revenue could materially adversely affect our reputation. Such negative publicity also could have an adverse effect on our ability to attract and retain consumers, patients, business partners or employees, and result in decreased revenue, which would materially adversely affect our business, financial condition and results of operations.

If the perception of our brands or business reputation is damaged, customers and the ultimate user may not purchase Plenity, which could materially and adversely affect our business, financial condition and results of operations.

We are building our reputation on the efficacy of Plenity and the high-quality nature of the product, its availability and the limited side effects. We must protect and expand on the value of Plenity to continue to be successful in the future. Any incident that erodes consumer or patient affinity for Plenity could significantly reduce our value and damage our business. For example, negative

third-party reports regarding Plenity, related side effects or the quality and availability of the product generally, whether accurate or not, may adversely affect consumer and patient perceptions, which could cause our value to suffer and adversely affect our business. In addition, if we are forced or voluntarily elect to recall Plenity or there are other regulatory actions taken with respect to Plenity, the public perception of the quality, safety and efficacy of Plenity may be diminished. We may also be adversely affected by news or other negative publicity, regardless of accuracy, regarding other aspects of our business, such as public health concerns, illness, safety, security breaches of personal information or employee information, employee-related claims relating to alleged employment discrimination, health care and benefits issues or government or industry findings about our retailers, distributors, manufacturers or others across the industry supply chain.

As part of our marketing initiatives, we have contracted with certain public figures to market and endorse our products. While we maintain specific selection criteria and are diligent in our efforts to seek out public figures that resonate genuinely and effectively with our consumer audience, the individuals we choose to market and endorse Plenity may fall into negative favor with the general public. Because our consumers may associate the public figures that market and endorse Plenity with us, any negative publicity on behalf of such individuals may cause negative publicity about us and Plenity. This negative publicity could materially and adversely affect our brands and reputation and our revenue and profits.

A significant interruption in the operations of our third-party partners could potentially disrupt our operations and have a material adverse effect on our business, financial condition and results of operations.

We rely on Roman Health Pharmacy LLC to provide our members with access to telehealth services and we partner with GoGoMeds to provide online pharmacy access to Plenity for non-telehealth patients. Although our ability to attract, retain, and serve our members is significantly dependent upon the reliable performance of our third party partners and their respective underlying information technology, we have limited control over their operations. Any significant disruption of their operations, whether as a result of general market or economic conditions, the failure of their equipment or information technology systems, a breach of data security or unauthorized disclosures of sensitive data, such as personally identifiable information or individually identifiable health information, could result in a decrease in consumer demand for Plenity. In addition, any disruption in the operations of our business partners could subject us to reputational damage and have a material adverse effect on our business, financial condition and results of operations.

Negative information, including inaccurate information about us on social media, which may include information attributable to spokespersons with whom we have a relationship, may harm our reputation and brand, which could have a material adverse effect on our business, financial condition and results of operations.

There has been a marked increase in the use of social media platforms and similar channels, including the use of celebrity endorsements or spokespersons with whom we may have a relationship, that provide individuals with access to a broad audience of consumers and other interested persons. The availability of information on social media platforms is virtually immediate, as is its effect. Many social media platforms immediately publish the content their subscribers and participants post, often without filters or checks on accuracy of the content posted. The opportunity for dissemination of information, including inaccurate information, is potentially limitless. Information about our business and Plenity may be posted on such platforms at any time. Negative views regarding Plenity and its efficacy may continue to be posted in the future, and are out of our control. Regardless of their accuracy or authenticity, such information and views may be adverse to our interests and may harm our reputation and brand. The harm may be immediate without affording an opportunity for redress or correction. Ultimately, the risks associated with any such negative publicity cannot be eliminated or completely mitigated and may materially and adversely affect our business, financial condition and results of operations.

We must expend resources to maintain consumer awareness of Plenity, build brand loyalty and generate increasing sales. Our marketing strategies and channels will evolve and our programs may or may not be successful.

To remain competitive and expand, we may need to increase our marketing and advertising spending to maintain and increase consumer awareness of Plenity, protect and grow our existing market share or promote new products, which could affect our operating results. Substantial advertising and promotional expenditures may be required to maintain or improve our brand's market position or to introduce new products to the market or new indications for Plenity, when and if available, and participants in our industry are increasingly engaging with non-traditional media, including consumer outreach through social media, celebrity promotions and web-based channels, which may not prove successful and may have a negative impact on perception of Plenity or reduce market acceptance of Plenity. An increase in our marketing and advertising efforts may not maintain or increase our current reputation, or lead to increased brand awareness. Moreover, we may not maintain current awareness of our brand due to any potential fragmentation of our marketing efforts as we continue to focus on a particular target market for weight management patients. Our inability to increase or maintain sales of Plenity could negatively impact our ability to develop other indications for Plenity as well as other product offerings, which may have an adverse effect on our business, financial condition and results of operations.

If we do not continually enhance our brand recognition, increase distribution of Plenity, attract new patients and introduce new and innovative products, either on a timely basis or at all, our business may suffer.

The weight management industry is subject to rapid and frequent changes in consumer demands and preferences. Because consumers are constantly seeking new products and strategies to achieve their weight goals, our success relies heavily on our ability to enhance our brand awareness through the increased distribution of Plenity, by attracting new patients and by continuing to develop and market new and innovative products that build on Plenity's commercialization. Since Plenity is currently our only product offering, our ability to generate sales of Plenity and for it to achieve widespread market acceptance is essential to the success of our business. To respond to new and evolving consumer demands and preferences, continue to enhance brand recognition and keep pace with new weight management, technological and other developments, we must constantly introduce new and innovative products into the market, after regulatory approval, some of which may not be accepted by consumers, or may not be achieved in a timely manner that allows us to build off of the commercialization of Plenity. If we cannot commercialize Plenity or other new products, our revenue may not grow as expected, which would materially and adversely affect our business, financial condition and results of operations.

If our security measures fail or are breached and unauthorized access to personal information and data is obtained, we may incur significant liabilities, our reputation may be harmed and we could lose sales, customers and patients.

Breaches of data security, website defacements and other malicious acts, which are increasingly negatively impacting companies, could result in unauthorized access to personal information or data, or cause interruptions to our manufacturing and supply chain for Plenity and therefore, limited supply of Plenity and access thereto. Such unauthorized access or interruptions could cause us to incur significant liabilities, harm our reputation, and may result in a decrease in sales and/or the loss of existing or potential customers and patients. We rely upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and utilize personal information and data, and it is critical that we do so in a secure manner to maintain the integrity of such personal information and data as well as to comply with applicable regulatory requirements and contractual obligations.

We also have outsourced the majority of elements that comprise our information technology infrastructure and, as a result, we manage multiple independent vendor relationships with third parties who may or could have access to the personal information and data that we collect. The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to security breaches. While we have invested, including by maintaining cybersecurity insurance coverage, and developed systems and processes designed to protect such proprietary or customer information or data, these measures are costly, and there can be no assurance that our efforts will prevent service interruptions or security breaches.

Existing, proposed or new data privacy legislation and regulations, including interpretations thereof, could also significantly affect our business. Data protection and privacy laws have been enacted by the U.S. federal and state governments, including the California Consumer Privacy Act (CCPA), which became effective on January 1, 2020, the Health Insurance Portability and Accountability Act (HIPAA), and other relevant statutes, as well as in Europe, including the European Genera Data Protection Regulation, which took effect in May 2018. These laws also typically include notification obligations and impose significant penalties and potential liability for non-compliance. The data privacy and security regulatory regime continues to evolve and is increasingly demanding. Many U.S. states are considering privacy and security legislation and there are ongoing discussions regarding a national privacy law. Variations in requirements across U.S. and foreign jurisdictions could present compliance challenges, and any failures to comply with such requirements may have an adverse effect on our business or results of operations.

Further, many jurisdictions require that customers be notified if a security breach results in the disclosure of their personal financial account or other information, and additional jurisdictions and governmental entities are considering such laws. In addition, other public disclosure laws may require that material security breaches be reported. If we experience, or in certain cases suspect, a security breach and such notice or public disclosure is required in the future, our reputation, brands and business may be harmed.

Prospective and existing customers and patients may have concerns regarding our use of personal information or data collected on our website, such as weight management information, financial data, email addresses and home addresses. These privacy concerns could keep customers and patients from using our website or purchasing Plenity, and third parties from partnering with us.

While no cybersecurity breach or attack to date has had a material impact on our business or results of operations, there can be no assurance that our efforts to maintain the security and integrity of our information technology networks and related systems will be effective or that attempted security breaches or disruptions would not be successful or damaging. In addition, the transmission of computer viruses, or similar malware, could adversely affect our information technology systems and harm our business operations. As a result, it may become necessary to expend significant additional amounts of capital and other resources to protect against, or to alleviate, problems caused by security breaches. These expenditures, however, may not prove to be a sufficient protection or remedy and our business, financial condition and results of operations could be materially and adversely impacted.

Any failure of our technology or systems to perform satisfactorily could result in an adverse impact on our business.

We rely on software, hardware, network systems and similar technology, including cloud-based technology, that is licensed from or maintained by third parties to operate our websites, to access Plenity and other services and products to support our business operations, including our manufacturing and supply chain operations. As much of this technology is complex, there may be future errors, defects or performance problems, including when we update our technology or integrate new technology to expand and enhance our capabilities. Our technology may malfunction or suffer from defects that become apparent only after extended use. The integrity of our technology may also be compromised as a result of third-party cyber-attacks, such as hacking, spear phishing campaigns and denial of service attacks, which are increasingly negatively impacting companies. In addition, our operations depend on our ability to protect our information technology systems against damage from third-party cyber-attacks, fire, power loss, water, earthquakes, telecommunications failures and similar unexpected adverse events. Disruptions in our websites, services and products or network systems could result from a number of factors, including unknown technical defects, insufficient capacity and the failure of our third-party providers to provide continuous and uninterrupted service. Such disruptions would be most impactful if they reduced accessibility to Plenity, including by delaying or halting the manufacture of Plenity and access to our supply chain. While we maintain disaster recovery capabilities to return to normal operation in a timely manner and we deploy multiple parallel instances of our applications across multiple computer resources, we do not have a fully redundant system that includes an instantaneous recovery capability. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner, which could have an adverse impact on our business.

As a result of such possible defects, failures, interruptions or other problems, Plenity could be rendered unreliable or be perceived as unreliable by customers, which could result in harm to our reputation and brands. Any failure of our technology or systems could result in an adverse impact on our business.

We may acquire businesses or products or form strategic alliances in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that following any such acquisition we will achieve the expected synergies to justify the transaction.

Our international operations for the supply chain and manufacture of Plenity pose certain political, legal and compliance, operational, regulatory, economic and other risks to our business that may be different from or more significant than risks associated with our U.S. operations.

The international nature of our operations for the supply chain and manufacture of Plenity involves a number of risks, including changes in U.S. and foreign regulations, tariffs, taxes and exchange controls; economic downturns; inflation and political and social instability in the countries in which we operate; weakening or loss of the protection of intellectual property rights in some countries and limitations on our ability to enforce our intellectual property rights under some local laws; and our dependence on foreign personnel. Foreign regulations may also restrict our ability to operate in some countries, acquire new businesses or repatriate cash from foreign subsidiaries back to the United States. If we expand our operations into additional foreign countries, we may be subject to additional risks, including the ability to successfully adapt to local culture and navigate regulatory, economic, political, social and intellectual property risks. We cannot be certain that we will be able to enter and successfully compete in additional foreign markets or that we will be able to continue to compete in the foreign markets in which we currently operate.

Inflation could adversely affect our financial results.

If inflation continues or worsens, it could negatively impact us by increasing our operating expenses. Inflation may lead to cost increases in multiple areas across our business, for example, rises in the prices of raw materials and manufactured goods, increased energy rates, as well as increased wage pressures and other expenses related to our employees. In particular, where we have agreed to undertake infrastructure build outs on a fixed budget for our carrier customers or by accepting government grants, inflation may result in build costs that exceed our original budget given the long delays experienced in procuring equipment and materials due to global supply chain delays. To the extent that we are unable to pass on these costs through increased prices, revised budget estimates, or offset them in other ways, they may impact our financial condition and cash flows.

Foreign currency exchange rate fluctuations could adversely affect our business, financial condition and results of operations.

A significant portion of our operating costs are denominated in foreign currencies. We are therefore exposed to fluctuations in the exchange rates between the U.S. dollar and the currencies in which our foreign operations pay expenses. We do not currently hedge, and have not historically hedged, our exposure to foreign currency fluctuations. Our consolidated financial results are presented in U.S. dollars and therefore, the assets and liabilities of our non-U.S. subsidiaries are translated into U.S. dollars at the exchange rates in effect at the balance sheet date. Expenses are translated into U.S. dollars at the average exchange rate for the period. Translation adjustments arising from the use of differing exchange rates from period to period are recorded in shareholders' equity as accumulated other comprehensive income (loss). Translation adjustments arising from intercompany receivables and payables with our foreign subsidiaries are generally recorded as a component of other expense (income). Accordingly, changes in currency exchange rates will cause our operating costs, net income and shareholders' equity to fluctuate and could adversely affect our business, financial conditions and results of operations.

Competition from other weight management and wellness industry participants or the development of more effective or more favorably perceived weight management methods could result in decreased demand for Plenity.

The weight management and wellness industry is highly competitive. We compete against a wide range of providers of weight management services and products and wellness industry participants. Our competitors include: commercial weight management programs; weight loss and wellness apps; surgical procedures; the pharmaceutical industry; the genetics and biotechnology industry; self-help weight management regimens and other self-help weight management products, services and publications, such as books, magazines, websites and social media influencers and groups; dietary supplements and meal replacement products; healthy living services, coaching, products, content and publications; weight management services administered by doctors, nutritionists and dieticians; government agencies and non-profit groups that offer weight management services; fitness centers; and national drug store chains. As we or others develop new or different weight management services, products, methods or technologies, additional competitors may emerge. Furthermore, existing competitors may enter new markets or expand their current offerings or advertising and marketing programs. More effective or more favorably perceived diet and weight management methods, including pharmaceutical treatments, fat and sugar substitutes or other technological and scientific advancements in weight management methods, also may be developed. This competition may reduce demand for Plenity.

The purchasing decisions of weight management and healthy living consumers are highly subjective and can be influenced by many factors, such as brand image, marketing programs, cost, social media presence and sentiment, consumer trends, the digital platform, content and user experience and perception of the efficacy of the product offerings. Moreover, consumers can, and frequently do, change approaches easily and at little cost. Any decrease in demand for Plenity may adversely affect our business, financial condition or results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could have a material adverse effect on our operations.

Changes in federal, state, local or foreign tax law or interpretations of existing tax law, or adverse determinations by tax authorities, could increase our tax burden or otherwise adversely affect our financial condition, results of operations or cash flows.

We are subject to taxation at the federal, state and local levels in the U.S. and other countries and jurisdictions. Our future effective tax rate could be affected by changes in the composition of earnings in jurisdictions with differing tax rates, changes in statutory rates and other legislative changes, changes in the valuation of our deferred tax assets and liabilities, or changes in determinations regarding the

jurisdictions in which we are subject to tax. From time to time, the U.S. federal, state and local and foreign governments make substantive changes to tax rules and their application, which could result in materially higher taxes than would be incurred under existing tax law or interpretation and could adversely affect our profitability, financial condition, results of operations or cash flows. State and local tax authorities have also increased their efforts to increase revenues through changes in tax law and audits. Such changes and proposals, if enacted, could increase our future effective income tax rates. We are subject to ongoing and periodic tax audits and disputes in various jurisdictions. An unfavorable outcome from any tax audit could result in higher tax costs, penalties and interest, thereby adversely impacting our financial condition, results of operations or cash flows.

Global economic, political and social conditions and uncertainties in the markets that we serve, including risks and uncertainties caused by the COVID-19 pandemic, may adversely impact our business.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including risks and uncertainties caused by the COVID-19 pandemic, including, weakened demand for any of our future products and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also result in supply disruption or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Natural or man-made disasters and other similar events may significantly disrupt our business and negatively impact our business, financial condition and results of operations.

Our ability to make, move and sell products in coordination with our suppliers, manufacturer and business partners is critical to our success. Damage or disruption to our collective supply, manufacturing or distribution capabilities resulting from weather, any potential effects of climate change, natural disaster, pandemics (such as the COVID-19 pandemic) or other outbreaks of contagious diseases, fire, explosion, cyber-attacks, terrorism, strikes, repairs or enhancements at facilities manufacturing or delivering Plenity or other reasons could impair our ability to manufacture, sell or timely deliver Plenity to customers and patients.

We rely on a limited number of third party suppliers to provide certain components and packaging materials, and currently have two manufacturing facilities in southern Italy. Adverse events affecting such suppliers or manufacturers may limit our ability to obtain such raw materials, or alternatives for these raw materials, at competitive prices, or at all. Competitors can be affected differently by weather conditions and natural disasters depending on the location of their suppliers and operations. Failure to take adequate steps to reduce the likelihood or mitigate the potential impact of such events, or to effectively manage such events if they occur, particularly when a component or packaging material is sourced from a single location or supplier or produced by a single manufacturer, could adversely affect our business, financial condition, results of operations and/or require additional resources to restore our supply chain or manufacturing capabilities, as applicable.

Risks Related to Ownership of Our Common Stock

An active trading market for our Common Stock may never develop or be sustained, which may make it difficult to sell the shares of our Common Stock you purchase.

An active trading market for our Common Stock may not develop or continue or, if developed, may not be sustained, which would make it difficult for you to sell your shares of our Common Stock at an attractive price (or at all). The market price of our Common Stock may decline below your purchase price, and you may not be able to sell your shares of our Common Stock at or above the price you paid for such shares (or at all).

The NYSE has delisted our Public Warrants and may delist our Common Stock from trading on its exchange, which could limit investors' ability to make transactions in our Common Stock and subject us to additional trading restrictions.

Our Common Stock is currently listed on the NYSE. In order for our Common Stock to continue to be listed on the NYSE, we are required to comply with various continued listing standards, On November 2, 2022, we received a letter from the NYSE indicating that we were not in compliance with the continued listing standard set forth in Section 802.01C of the NYSE Listed Company Manual because the average closing price of our Common Stock fell below $1.00 per share over a period of 30 consecutive trading days (the "minimum share price requirement"). Subject to certain exceptions set forth in the NYSE rules, if we are unable to satisfy the NYSE requirement that our stock price return to a level over $1.00 by May 2, 2023, we will be subject to the NYSE's suspension and delisting procedures. Additionally, on March 18, 2023, NYSE notified us that they had considered the closing price of $0.11 of our Common Stock on March 17, 2023 to be close to an "abnormally low selling price" under Section 802.01D of the NYSE Listed Company Manual and that continued trading at such low price could result in immediate delisting of our Common Stock. On March 18, 2023, NYSE also indicated that there is a potential for us to fall below the $15 million 30-trading-day average market

capitalization standard under Section 802.01B of the NYSE Listed Company Manual which could result in immediate delisting of our Common Stock. We are closely monitoring the closing share price of our common stock and are considering all available options. We intend to regain compliance with the minimum share price requirement by pursuing measures that are in the best interest of the Company and our shareholders. The last reported sale price of our Common Stock on the NYSE on March 24, 2023 was $0.17 per share.

However, if we fail to regain compliance with the minimum share price requirement or we fail to meet other requirements for continued listing on the NYSE, the NYSE may take steps to delist our Common Stock and/or Public Warrants. If the NYSE delists our securities for failure to meet the listing standards, we and our stockholders could face significant material adverse consequences including:

- limited availability of market quotations for our securities;
- a determination that our Common Stock is a "penny stock" which will require brokers trading in our Common Stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our Common Stock;
- a limited amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Such a delisting would impair your ability to sell or purchase our securities when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our securities to become listed again, stabilize the market price or improve the liquidity of our securities, or prevent future non-compliance with NYSE's listing requirements.

Additionally, in January 2023, we received written notice from the NYSE that the NYSE suspended trading in, and had determined to delist, our Public Warrants from the NYSE. The delisting was a result of "abnormally low" price levels of the warrants pursuant to Section 802.01D of the NYSE Listed Company Manual. The delisting was effective as of January 20, 2023, and the Public Warrants are no longer listed on the NYSE.

The price of our Common Stock has been, and may continue to be, volatile, and you could lose all or part of your investment.

The market price and trading volume of our Common Stock has been, and may continue to be, highly volatile and the price of our Common Stock has declined substantially. To date, the closing price of our Common Stock has fluctuated from a high of $10.78 on February 9, 2021 to a low of $0.11 per share on March 17, 2023. To date, daily trading volume ranged from approximately zero to 9,578,900 shares. Continued volatility in the market price and trading volume of our Common Stock could cause purchasers of our Common Stock to incur substantial losses. The market price and trading volume of our Common Stock could continue to remain volatile for many reasons, including in response to the risks described herein and in the other filings we make with the SEC, or for reasons unrelated to our operations, many of which may be beyond our control, such as:

- our inability to raise funding and any corresponding reduction in our marketing efforts;
- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturing operations and plans;
- our ability to generate sufficient patient demand for our product and product candidates;
- our inability to establish collaborations, if needed;
- our failure to continue to commercialize Plenity and our other product candidates;
- departures of key scientific, commercial or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;

- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our Common Stock by us or our stockholders in the future;
- trading volume of our Common Stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or shareholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

The stock market, the NYSE and biotechnology companies, in recent years, and during the COVID-19 pandemic in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Common Stock, regardless of our actual operating performance. Continued declines in the market price of our Common Stock have, among other things, made it more difficult to raise capital on terms acceptable to us, or at all, and may make it difficult for our investors to sell their Common Stock. In addition, in the past, securities class action litigation has often been instituted against companies following periods of volatility in, or significant market price decline of, a company's securities. This type of litigation, if instituted against us, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, financial condition and results of operations.

Securities of many companies formed through a merger or other business combinations with a SPAC, such as ours, have experienced a material decline in price relative to the share price of the SPAC prior to the Business Combination and may continue to experience high price volatility.

As with many SPAC initial public offerings in recent years, our predecessor CPSR issued shares and warrants for $10.00 per unit upon the closing of its July 2020 initial public offering. As with other SPACs, the $10.00 unit price reflected each share having a one-time right to redeem such share for a pro rata portion of the proceeds held in the trust account prior to the Closing of the Business Combination. Following the Closing of the Business Combination, the shares outstanding no longer have any such redemption right and the market price of such shares are now solely dependent upon the fundamental value of our company. Similar to the securities of many other companies formed through a merger or other business combination with a SPAC in recent years, the market price of our securities is currently significantly less than the $10.00 unit price of our predecessor. The last reported sale prices of our Common Stock on the NYSE on March 24, 2023 was $0.17 per share.

If securities or industry analysts do not publish research or reports about our business, if they adversely change their recommendations regarding our shares or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

The trading market of our Common Stock is influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over these analysts. If one or more of these analysts cease coverage of us or fail to publish

reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

Future sales of our Common Stock by us or existing stockholders, and issuances of our Common Stock or rights to purchase our Common Stock, including pursuant to the Gelesis Holdings, Inc. 2021 Stock Option and Incentive Plan and future exercise of warrants, could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.

The sale of substantial amounts of shares of our Common Stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of our Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Pursuant to our resale registration statement on Form S-1, declared effective on June 7, 2022 and following the expiration of otherwise applicable lock-ups on January 13, 2023, stockholders who held our capital stock prior to our Business Combination, or who received shares in connection with our Business Combination, other than certain shares of our Common Stock held by our affiliates (or affiliates of our predecessor), now hold freely tradable shares of our Common Stock without restriction or further registration requirements under the Securities Act, and therefore they may take steps to sell their shares. Additionally, any shares of Common Stock held by our affiliates (or affiliates of our predecessor) will be eligible for resale pursuant to Rule 144 under the Securities Act, subject to the volume, manner of sale, holding period and other limitations of Rule 144.

In addition, we expect that significant additional capital may be needed in the future to continue our planned operations, including continued commercialization of Plenity, expanding commercial operations, self-commercialization of our products in new markets, conducting clinical trials, expanded research and development activities, and costs associated with operating as a public company. To raise capital, we may sell shares of our Common Stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell shares of our Common Stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights, preferences, and privileges senior to existing holders of our Common Stock.

Pursuant to the Gelesis Holdings, Inc. 2021 Stock Option and Incentive Plan (the "Equity Incentive Plan"), we are authorized to grant equity awards to our employees, directors and consultants. Initially, the aggregate number of shares of Common Stock that may be issued pursuant to share awards under the Equity Incentive Plan is equal to eight percent (8%) of the fully diluted shares of Common Stock as of immediately following the Effective Time. The Equity Incentive Plan also provides that the number of shares of Common Stock reserved for issuance thereunder will automatically increase annually on the first day of each calendar year, beginning on January 1, 2023, by an amount equal to four percent (4%) of the number of shares of Common Stock outstanding on December 31 of the immediately preceding calendar year or such lesser amount as determined by the administrator of the Equity Incentive Plan. Unless our Board elects not to increase the number of shares available for future grants each year, our shareholders may experience additional dilution, which could cause our share price to fall.

We filed a registration statement on Form S-8 to register shares of our common stock issued or reserved for issuance under the Equity Incentive Plan. Subject to the satisfaction of vesting conditions, shares of Common Stock registered under the registration statement on Form S-8 generally became available for resale immediately in the public market without restriction.

We have also agreed to file a resale registration statement covering the resale by B. Riley of shares of Common Stock that we may issue to B. Riley in an aggregate amount of up to the lesser of (i) $50.0 million and (ii) an amount not to exceed 14,506,475 shares of Common Stock (such number of shares equal to approximately 19.99% of the aggregate number of shares of Common Stock issued and outstanding immediately prior to the execution of the CEF Purchase Agreement) in connection with our Committed Equity Facility. The price for any sale of our shares of Common Stock by us to B. Riley pursuant to the Committed Equity Facility would be pursuant to a formula set forth in the CEF Purchase Agreement providing for the purchase of such shares at a discount to the volume-weighted average purchase price of our Common Stock contemporaneous with such sale. If and when we sell shares of Common Stock to B. Riley under the program, after B. Riley has acquired the shares, it may resell all, some, or none of such shares at any time or from time to time in its discretion. Therefore, sales to B. Riley would result in dilution to our existing stockholders and the resale thereof by B. Riley may have a negative impact on the market price of our Common Stock. Further, given this substantial number of shares are potentially available for resale, the sale of shares by B. Riley, or the perception in the market that B. Riley intends to sell shares, could increase the volatility of the market price of our Common Stock or result in a decline in the market price of our Common Stock.

In addition, as of the date of this Form 10-K, our Common Stock is also subject to potential dilution from the exercise of up to 24,733,365 warrants, the exercise of up to 14,101,702 stock options, the issuance of common stock pursuant to the vesting of up to 4,685,166 restricted stock units, the issuance of up to 23,482,845 earnout shares pursuant to the triggering events in the Business

Combination Agreement, and the potential Common Stock is also subject to potential dilution upon issuance of Common Stock in connection with future equity and or convertible debt financings, including the 2022 Promissory Notes. Sales of substantial numbers of such shares in the public market, including the resale of the shares of Common Stock held by our stockholders, could adversely affect the market price of our Common Stock, the impact of which is increased as the value of our stock price increases.

If certain holders of our Common Stock sell a significant portion of their securities, it may negatively impact the market price of the shares of our Common Stock and such holders still may receive significant proceeds.

As of the date of this Form 10-K, the market price of our Common Stock is below $10.00 per share, which was the price per unit sold in the initial public offering of our predecessor, CPSR, the per-share price of the 9,000,000 shares of CPSR Class A Common Stock our predecessor sold to certain investors in connection with our Business Combination in a private placement for an aggregate amount of $90.0 million (the "PIPE Financing") and also the per share value of the consideration issued to Legacy Gelesis shareholders upon consummation of our Business Combination. However, certain of our shareholders who hold shares of our Common Stock that were (i) originally purchased by our predecessor's sponsor, Capstar Sponsor Group, LLC, in a private placement prior to our predecessor's initial public offering (the "Founder Shares") or (ii) originally issued by CPSR in a private placement in connection with Backstop Agreement, dated December 30, 2021 (the "Backstop Agreement"), between CPSR and certain investors (the "Backstop Shares"), may nonetheless be inclined to sell such Founder Shares or Backstop Shares as they were originally purchased at an effective price significantly less than $10.00 per share. The currently outstanding 4,916,250 Founder Shares were purchased at an effective price of $0.0051 per share. Holders of the Backstop Shares purchased an aggregate of 744,217 shares of CPSR Class A Common Stock in a private placement at a price of $10.00 per share, for an aggregate purchase price of $7.4 million and such holders also received an aggregate of 1,983,750 shares of CPSR Class A Common Stock as additional consideration, resulting in an effective purchase price for the currently outstanding 2,727,967 Backstop Shares of approximately $2.73 per share. Accordingly, holders of the Founder Shares and Backstop Shares could sell their securities at a per-share price that is less than $10.00 and still realize a significant profit from the sale of those securities that could not be realized by our other shareholders. On March 24, 2023, the closing price of our Common Stock was $0.17. Based on this closing price, the aggregate sales price of the Founder Shares would be approximately $0.8 million and the aggregate sales price of the Backstop Shares would be approximately $0.5 million.

Pursuant to the Registration Rights Agreement dated January 13, 2022, by and among us, certain former stockholders of Legacy Gelesis, Capstar Sponsor Group, LLC and certain directors and officers of our predecessor, CPSR, we have filed a registration statement, declared effective by the SEC on June 7, 2022, which registers for resale the Founder Shares and certain additional shares our Common Stock held by certain of our other stockholders.

The holders of our recently issued 2022 Promissory Notes have certain additional rights upon an event of default under such notes which could cause material dilution to investors and a decline in our stock price.

On July 25, 2022 and August 4, 2022 we issued the 2022 Promissory Notes to the Promissory Note Investors, each a beneficial owner of more than 5% of our Common Stock, for an aggregate cash purchase price of $25.0 million. Each 2022 Promissory Note contains certain customary events of default including, without limitation, our failure to pay amounts due thereunder (a "Payment Default"). If a Payment Default occurs and is continuing under an Investor's 2022 Promissory Note, such Investor may declare the unpaid principal and accrued interest due and payable. If a Payment Default is not cured by us after five days, (x) we will be required to issue a warrant to the Investor holding such 2022 Promissory Note (a "Promissory Note Warrant") to purchase, at an exercise price of $0.01 per share, subject to adjustment, an aggregate number of shares of Common Stock equal to: (i) (A) 0.2 multiplied by (B) the amount of outstanding principal and accrued interest under such 2022 Promissory Note as of the date of conversion divided by (ii) the volume weighted average price of the Common Stock, as reported by the NYSE, for the five (5) trading days (the "Common Stock VWAP") occurring immediately prior to the date of exercise and (y) such Investor may elect, at its option, to convert the outstanding principal and accrued interest under the 2022 Promissory Notes into a number of shares of Common Stock equal to (i) the amount of outstanding principal and accrued interest under the 2022 Promissory Note as of the date of conversion, divided by (ii) the lesser of the price per share of (A) the Common Stock, as reported by the NYSE or (B) the Common Stock VWAP as of the day prior to the date of such Investor's conversion notice. The number of shares of Common Stock issuable upon exercise of Promissory Note Warrants and/or conversion of 2022 Promissory Notes following a Payment Default will be calculated based on the market price per share of our Common Stock at the time of exercise/conversion, however, any such issuance may result in (i) increased beneficial ownership of our shares and increased voting power for the Investors, (ii) material dilution in the value of the remaining outstanding shares of our Common Stock and the voting power represented thereby and (iii) a decline in the market price of our Common Stock. In addition, any sales in the public market of the Common Stock issuable upon such exercise or conversion of Promissory Note Warrants or 2022 Promissory Notes, as applicable, could adversely affect the market price of our Common Stock.

The financial and operational projections and commercialization and product candidate development timelines that we may provide from time to time are subject to inherent risks.

The projections and timelines that our management may provide from time to time (including with respect to financial or operational matters, commercialization efforts or product candidate development) reflect numerous assumptions made by our management with respect to our specific, as well as general, ability to raise additional capital, and other matters, all of which may be difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate or, in the event we do not successfully raise additional capital, that our commercialization or product development activities may be curtailed. There may be differences between actual and projected results from time to time. Our future actual results may be materially different from those contained in our projections, both as to amounts and as to timing. Further, if our commercialization or product development activities are slowed or stopped, we will likely be unable to meet the timelines and projections we have previously provided. The inclusion of projections or timelines in (or incorporated by reference in) this Form 10-K or any other filing we make with the SEC periodically should not be regarded as an indication that we or our management or representatives considered or consider such projections and timelines to be a reliable prediction of future events, and the projections and timelines should not be relied upon as such.

We do not intend to pay dividends on our Common Stock, so any returns will be limited to the value of our Common Stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibit or limit the amount of dividends that may be declared or paid on our Common Stock. Any return to shareholders will therefore be limited to the appreciation of their shares of Common Stock, which may never occur.

We are an emerging growth company, and it cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our Common Stock less attractive to investors.

We are currently an "emerging growth company" within the meaning of the Securities Act, as modified by the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act ("Section 404"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As a result, our shareholders may not have access to certain information they may deem important. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our consolidated financial statements with another public company, which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period, difficult or impossible because of the potential differences in accounting standards used.

Further, even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our share price may be more volatile.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management has and will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and will incur significant legal, accounting, insurance and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC, and the NYSE to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say-on-pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five (5) years following the year in which CPSR completed its initial public offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Shareholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

These rules and regulations applicable to public companies have increased and will continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our Board committees, or as executive officers.

If we fail to maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with generally accepted accounting principles. We will continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to document, review and improve our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act and applicable United States laws, which will require annual management assessment of the effectiveness of our internal control over financial reporting. When we lose our status as an "emerging growth company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting. However, for so long as we remain an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate consolidated financial statements on a timely basis, could increase our operating costs and harm our business. In our efforts to maintain proper and effective internal control over financial reporting, we may discover significant deficiencies or material weaknesses in our internal control over financial reporting, which we may not successfully remediate on a timely basis or at all. Any failure to remediate any significant deficiencies or material weaknesses identified by us or to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations or result in material misstatements in our consolidated financial statements. If we identify one or more material weaknesses in our internal control over financial reporting in the future, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements, which may harm the market price of our Common Stock.

Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our Common Stock could decline, and we could be subject to sanctions or investigations by the NYSE, the SEC or

other regulatory authorities. Failure to remediate any material weakness in our internal control over financial reporting on a timely basis, if at all, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Delaware law and our Bylaws contain certain provisions, including anti-takeover provisions that limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable.

Our Bylaws and the Delaware General Corporation Law contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock, and therefore depress the trading price of our Common Stock. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the current members of our Board or taking other corporate actions, including effecting changes in our management. Among other things, the Organizational Documents include provisions regarding:

- the ability of our Board to issue shares of preferred stock, including "blank check" preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- our Board being classified into three classes, with only one class being elected each year to serve three-year terms. As a result, in most circumstances, a person can gain control of our Board only by successfully engaging in a proxy contest at two or more annual stockholders meetings;
- the Certificate of Incorporation's prohibition on cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the limitation of the liability of, and the indemnification of, our directors and officers;
- the ability of our Board to amend the Bylaws, which may allow our Board to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the Bylaws to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our Board or to propose matters to be acted upon at a stockholders' meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in our Board and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our Board or management.

Our Bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with our Company or our Company's directors, officers, or other employees.

Our Bylaws require, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, that derivative actions brought in our name, actions against our directors, officers, other employees or stockholders for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware.

Unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will, to the fullest extent permitted by applicable law, be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the rules and regulations promulgated thereunder. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Alternatively, if a court were to find the choice of forum provision contained in our Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

Our Bylaws provide that the exclusive forum provision will be applicable to the fullest extent permitted by applicable law, subject to certain exceptions. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations promulgated thereunder. As a result, the exclusive forum provision

will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, our Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the rules and regulations promulgated thereunder. We note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our Common Stock has been volatile and, in the past, companies that have experienced volatility in the market price of their stock, particularly companies who have recently "gone public" through a merger or other business combination with a special purpose acquisition company ("SPAC"), have been subject to securities class action litigation. Stockholder activism, which could take many forms or arise in a variety of situations, has also been increasing recently. Volatility in the market price of our Common Stock or other reasons may cause us to become the target of this type of litigation or stockholder activism in the future. Securities litigation against us and stockholder activism could result in substantial costs and divert management's attention from other business concerns, which could seriously harm our business. Additionally, such securities litigation and stockholder activism could give rise to perceived uncertainties as to our future and make it more difficult to attract and retain qualified personnel. We may be required to incur significant legal fees and other expenses related to any securities litigation or activist stockholder matters. Further, the market price of our Common Stock could be adversely affected by the events, risks and uncertainties of any securities litigation or stockholder activism.

The exercise of our Warrants for shares of our Common Stock would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

We have previously filed a Form S-1 prospectus to register (i) 13,800,000 outstanding Public Warrants to purchase 13,800,000 shares of our Common Stock exercisable at an exercise price of $11.50 per share commencing thirty (30) days following the Closing; (ii) 7,520,000 outstanding Private Warrants to purchase 7,520,000 shares of our Common Stock, exercisable at an exercise price of $11.50 per share commencing thirty (30) days following the Closing and (iii) 3,189,49 currently exercisable Rollover Warrants, 1,353,062 of which are exercisable at an exercise price of $1.45 and 1,836,429 of which are exercisable at an exercise price of $0.02. In connection with the CMS License Agreement Amendment, we issued to CMS a warrant to purchase 400,000 shares of our Common Stock, exercisable at an exercise price of $0.01 per share immediately upon issuance. In addition, Promissory Note Warrants (as defined above) may potentially be issued in connection with a Payment Default (as defined above) under our Promissory Notes. To the extent any such warrants are exercised, additional shares of our Common Stock will be issued, which will result in dilution to the holders of our Common Stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of our Common Stock, the impact of which is increased as the value of our stock price increases.

We may redeem your unexpired Public Warrants prior to their exercise at a time that is disadvantageous to you, thereby making your warrants worthless.

We will have the ability to redeem outstanding Public Warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, provided that the closing price of our Common Stock equals or exceeds $18.00 per share for any twenty (20) trading days within a thirty (30) trading-day period ending on the third trading day prior to the date we give notice of redemption. If and when such warrants become redeemable, we may exercise the redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of such warrants could force holders to (i) exercise the warrants and pay the exercise price therefor at a time when it may be disadvantageous to do so, (ii) sell the warrants at the then-current market price when the holder might otherwise wish to hold onto such warrants or (iii) accept the nominal redemption price which, at the time the outstanding warrants are called for redemption, is likely to be substantially less than the market value of the warrants. None of the Private Placement Warrants will be redeemable by us so long as they are held by their initial purchasers or their permitted transferees.

In addition, we may redeem the Public Warrants after they become exercisable for a number of shares of our Common Stock determined based on the redemption date and the fair market value of our Common Stock. Any such redemption may have similar consequences to a cash redemption described above. In addition, such redemption may occur at a time when the warrants are "out-of-the- money," in which case you would lose any potential embedded value from a subsequent increase in the value of our Common Stock had such warrants remained outstanding.

Our Private Warrants are being accounted for as a warrant liability and are being recorded at fair value upon issuance with changes in fair value each period reported in earnings, which may have an adverse effect on the market price of our Common Stock.

Under GAAP, we are required to evaluate our Warrants to determine whether they should be accounted for as a warrant liability or as equity. We have concluded that the Private Warrants contain provisions requiring liability classification. Therefore, we are accounting for the Private Warrants as a warrant liability and are recording that liability at fair value upon issuance. We will record any subsequent changes in fair value as of the end of each period for which earnings are reported. The impact of changes in fair value on earnings may have an adverse effect on the market price of our Common Stock and may cause fluctuations in our results of operations based on factors that are outside of our control.

There can be no assurance that our Warrants will be in the money at the time they become exercisable; they may expire worthless and therefore we may not receive cash proceeds from the exercise of Warrants.

As of the date of this Form 10-K, we have (i) 13,800,000 outstanding Public Warrants to purchase 13,800,000 shares of our Common Stock, exercisable at an exercise price of $11.50 per share, which expire on the earlier to occur of January 13, 2027 or redemption; (ii) 7,520,000 outstanding Private Warrants to purchase 7,520,000 shares of our Common Stock, exercisable at an exercise price of $11.50 per share, which expire on the earlier to occur of January 13, 2027 or redemption; (iii) 3,013,365 exercisable Rollover Warrants, 1,353,062 of which are exercisable at an exercise price of $1.45 and expire on October 21, 2030 and 1,660,303 of which are exercisable at an exercise price of $0.02 and expire on February 15, 2025; and (iv) 400,000 warrants issued to CMS which are exercisable at an exercise price of $0.01 and expire on August 4, 2032.

The exercise of Warrants, and any proceeds we may receive from their exercise, are highly dependent on the price of our Common Stock and the spread between the exercise price of the warrant and the price of our Common Stock at the time of exercise. For example, to the extent that the price of our Common Stock exceeds $11.50 per share, it is more likely that holders of our Public Warrants and Private Warrants will exercise their warrants. If the price of our Common Stock is less than $11.50 per share, it is unlikely that such holders will exercise their warrants. As of March 24, 2023, the closing price of our Common Stock was $0.17 per share. There can be no assurance that all of our warrants will be in the money prior to their expiration. Our Public Warrants under certain conditions, as described in the warrant agreement, are redeemable by the Company at a price of $0.01 per warrant or on a cashless basis. Our Private Warrants are not redeemable so long as they are held by the initial stockholders and are exercisable on a cashless basis. Our Rollover Warrants and CMS Warrants are not redeemable and are exercisable on a cashless basis only with respect to the 1,660,303 Rollover Warrants that have an exercise price of $0.02. As such, it is possible that we may never generate any cash proceeds from the exercise of our Warrants.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Gelesis corporate headquarters are located in Boston, Massachusetts, where we occupy approximately 9,446 square feet of office space subleased from PureTech. We also operate manufacturing and research and development facilities in Italy, including a 51,000 square foot facility, which commenced commercial scale production in the fourth quarter of 2021 and which the Company expects to further expand to a 88,600 square foot facility, as well as approximately 12 acres of land, where we have initiated construction of an additional 207,000 square foot facility. Both facilities are near the Town of Lecce in the Puglia region of Italy.

Item 3. Legal Proceedings.

From time to time, we are party to litigation and subject to claims incident to the ordinary course of business. As our growth continues, we may become party to an increasing number of litigation matters and claims. The outcome of litigation and claims cannot be predicted with certainty, and the resolution of these matters could materially affect our future results of operations, cash flows, or financial position. We are not presently party to any legal proceedings that, in the opinion of management, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition, or cash flows.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

The CPSR shares of Class A common stock, units, and warrants were historically traded on the NYSE under the symbols "CPSR," "CPSR.U" and "CPSR WS," respectively. In connection with the Business Combination, the CPSR shares of Class A common stock converted into shares of common stock on a one-for-one basis. As of the date of this Form 10-K, our common stock is listed on the NYSE under the trading symbols of "GLS". In January 2023, our Public Warrants, which were previously listed under the ticker symbol "GLS WS" were delisted from the NYSE.

Holders

On March 23, 2023, there were 35 holders of record of our common stock and 14 holders of record of our Warrants.

Dividends

We have not paid any cash dividends on our common stock to date. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of our board of directors. In addition, our board of directors is not currently contemplating and does not anticipate declaring any share dividends in the foreseeable future. Further, if we incur any indebtedness, our ability to declare dividends may be limited by restrictive covenants we may agree to in connection therewith.

Securities Authorized for Issuance under Equity Compensation Plans

In connection with the Merger, our shareholders approved the Gelesis Holdings, Inc. 2021 Stock Option and Incentive Plan. We also assumed all outstanding awards under the Gelesis, Inc. 2016 Stock Option and Grant Plan and the Gelesis 2006 Stock Incentive Plan.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Offerings.

The securities issued in connection with the Business Combination, the PIPE Financing and the Backstop Agreement were not registered under the Securities Act in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

References to the "Company," "our," "us," "we," or "Gelesis" refer to Gelesis Holdings, Inc. and its consolidated subsidiaries (formerly known as Capstar Special Purpose Acquisition Corp. or "CPSR") following the Business Combination with Gelesis Inc., or Legacy Gelesis. The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with the consolidated financial statements and the notes thereto contained elsewhere in this Form 10-K. Certain of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-K, including information with respect to plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including, but not limited to, those set forth in the section entitled "Cautionary Note Regarding Forward-Looking Statements" in this Form 10-K and those set forth in the section entitled "Risk Factors" in Item 1A of Part I of this Form 10-K, actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we do not intend to update any of these forward-looking statements after the date hereof or to conform these statements to actual results or revised expectations. You should carefully read the sections entitled "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" in this Form 10-K to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We are a commercial stage biotherapeutics company built for consumer engagement. We are focused on advancing first-in-class superabsorbent hydrogel therapeutics for chronic gastrointestinal, or GI, diseases including excess weight, type 2 diabetes, NAFLD/NASH, functional constipation, and inflammatory bowel disease. Our biomimetic superabsorbent hydrogels are inspired by the composition and mechanical properties (e.g. firmness) of raw vegetables. They are conveniently administered in capsules taken with water to create a much larger volume of small, non-aggregating hydrogel pieces that become an integrated part of the meals, and act locally in the digestive system.

Our first commercial product, Plenity®, received *de novo* clearance from the FDA on April 12, 2019 to aid in weight management in adults with excess weight or obesity, Body Mass Index (BMI) of 25 to 40 kg/m^2, when used in conjunction with diet and exercise.

Plenity, which is available by prescription in the United States, became available for first commercial sale in May 2020 to a limited number of consumers. In October 2020 availability was increased to test commercial interest and consumer experience. Activities associated with a full commercial launch in the United States began in late 2021. In February 2022, we launched the first national broad awareness media campaign for the product and we continued to invest in broad awareness during the year ended December 31, 2022. While these are significant milestones, continued commercialization of Plenity will require significant external funding until we are able to generate positive cash flows from product sales.

Since our inception, we have devoted our resources to business planning, developing proprietary superabsorbent hydrogel manufacturing know-hows and technologies, preclinical and clinical development, commercial activities, recruiting management and technical staff and raising capital. We have funded our operations to date through proceeds from the issuance of redeemable convertible preferred stock, license and collaboration agreements, long-term loans, promissory notes, convertible senior secured notes, government grants and our January 2022 Business Combination, pursuant to which we received approximately $105.0 million of gross proceeds. We have incurred significant operating losses to date. Our net losses were $55.8 million and $93.3 million for years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $322.6 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future.

As a result, we will require substantial additional funding to support our continuing operations until we are able to generate positive cash flows from product sales. Until such time, we expect to finance our operations through equity offerings, debt financings or other capital sources, including collaborations, licenses, dealership partnerships or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. If we are unable to obtain funding, we may be forced to delay, reduce or eliminate some or all of our commercialization efforts, research and development programs or product pipeline expansion, which could adversely affect our business prospects, or we may be unable to continue operations.

As of the date of this Form 10-K, we expect that our existing cash and cash equivalents plus the $5 million of proceeds from the issuance of convertible senior secured notes in February 2023 will only be sufficient to fund our operations into the early second quarter of 2023, prior to considerations for any additional funding, and not at least twelve months beyond the date of issuance of the unaudited consolidated financial statements included elsewhere in this Form 10-K. As a result, we have concluded that there is

substantial doubt about our ability to continue as a going concern. Our unaudited consolidated financial statements included elsewhere in this Form 10-K, which have been prepared in accordance with accounting principles generally accepted in the United States ("US GAAP"), contemplate that we will continue to operate as a going concern. Our financial statements do not contain any adjustments that might result if we are unable to continue as a going concern. See "— Liquidity and Capital Resources" for further information**.**

Recent Events

Business Combination

On July 19, 2021, Gelesis, Inc. (together with its consolidated subsidiaries, "Legacy Gelesis") entered into a Business Combination Agreement (as amended on November 8, 2021 and December 30, 2021, the "Business Combination Agreement") with CPSR, a Delaware corporation and special purpose acquisition company, and CPSR Gelesis Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of CPSR ("Merger Sub"). On January 13, 2022, Legacy Gelesis, CPSR, and Merger Sub consummated the business combination ("Business Combination") pursuant to the terms of the Business Combination Agreement. Pursuant to the Business Combination Agreement, on the closing date, (i) Merger Sub merged with and into Legacy Gelesis (the "Merger"), with Legacy Gelesis as the surviving company in the Merger, and, after giving effect to such Merger, Legacy Gelesis became a wholly-owned subsidiary of CPSR and (ii) CPSR changed its name to "Gelesis Holdings, Inc." (together with its consolidated subsidiaries, "Gelesis Holdings"). The Business Combination, together with the PIPE Investment and the sale of the Backstop Purchase Shares, generated approximately $105 million in gross proceeds and $70.5 million in net proceeds (See Note 3). On January 14, 2022, Gelesis Holdings' common stock and public warrants began trading on the New York Stock Exchange ("NYSE") under the symbols "GLS" and "GLS.W", respectively.

The Business Combination was accounted for as a reverse recapitalization in conformity with accounting principles generally accepted in the United States. Under this method of accounting, CPSR has been treated as the "acquired" company for financial reporting purposes. This determination was primarily based on the Legacy Gelesis' stockholders comprising a relative majority of the voting power of the combined company, the Legacy Gelesis' operations prior to the acquisition comprising the only ongoing operations of Gelesis Holdings, the majority of Gelesis Holdings' board of directors appointment by Legacy Gelesis, and Legacy Gelesis' senior management comprising the entirety of the senior management of Gelesis Holdings. Accordingly, for accounting purposes, the consolidated financial statements of Gelesis Holdings will represent a continuation of the consolidated financial statements of Legacy Gelesis with the Business Combination being treated as the equivalent of Legacy Gelesis issuing stock for the net assets of CPSR, accompanied by a recapitalization. The net assets of CPSR have been stated at historical costs, with no goodwill or other intangible assets recorded.

Roman Health Pharmacy LLC Distribution Agreement Amendment

On June 14, 2022, we entered into a Third Amended and Restated Supply and Distribution Agreement with Ro to amend the agreement that granted Ro exclusive telehealth distributor rights to sell Plenity in the United States in the mail order/online pharmacy channel. Pursuant to the amended agreement, Ro's exclusive distributor rights to sell Plenity in the United States became exclusive only for consumers who seek an on-line consultation through myplenity.com in the United States and with respect to certain named competitors and/or third parties. Such rights will continue through July 1, 2023, consistent with the parties' prior agreement. In addition, pursuant to the amended agreement, we received $15.0 million in cash from Ro as a pre-buy commitment to purchase units of Plenity.

Promissory Notes and Promissory Note Warrants

On July 25, 2022 and August 4, 2022, we issued three term promissory notes in the aggregate principal amount of $25.0 million to existing investor CMS Bridging DMCC, an affiliate of CMS Medical Venture Investment (HK) Limited ("CMS"), and existing investors PureTech Health LLC ("PureTech") and SSD2 LLC ("SSD2"), for an aggregate cash purchase price of $25.0 million (the "2022 Promissory Notes"). Each of the 2022 Promissory Notes is unsecured and bears interest at a rate of 15% per annum. Each 2022 Promissory Note matures on the earlier of (a) December 31, 2023 or (b) five (5) business days following a qualified financing. Upon a payment default under any 2022 Promissory Note that has not been cured after five days (i) we will be required to issue certain warrants to the holders as defined by the 2022 Promissory Note agreements and (ii) the holders will have the option to convert outstanding principal and accrued interest into a number of shares of our Common Stock as defined by the 2022 Promissory Note agreements.

On February 21, 2023, we entered into a Note and Warrant Purchase Agreement with PureTech, pursuant to which we issued a short term convertible senior secured note in the aggregate principal amount of $5.0 million and warrants to purchase 23,688,047 shares of Common Stock. The warrants have an exercise price of $0.2744 and may not be exercised prior to the receipt of Stockholder approval. The short term convertible senior secured note bears interest at a rate of 12% per annum, and matures on July 31, 2023, unless earlier converted or the maturity is extended as described within the definitive Agreements.

CMS License Agreement Amendment and CMS Warrant

On August 4, 2022, we entered into an amendment to the License, Collaboration and Supply Agreement, dated June 18, 2020, by and between us and CMS. Pursuant to the amendment, the one-time, non-refundable, and non-creditable regulatory approval milestone payment of $5.0 million provided for in the original agreement became immediately payable. In addition, the amendment expands the CMS Territory to include Brunei, Myanmar, Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Thailand and Vietnam and provides that the minimum annual royalty term for CMS territory will commence January 2024 (rather than January 2022, as previously provided under the original agreement) and extend through the expiration date of the amended agreement.

Upon execution of the amendment, we also issued to CMS a warrant to purchase up to 400,000 shares of common stock, par value $0.0001 per share, at an exercise price of $0.01 per share. The warrant expires on the date that is ten years from the date of issuance and is exercisable at any time from the date of issuance until the expiration date**.**

One S.r.l. Amended Warrant Purchase Agreement

On August 9, 2022, we entered into an amendment to the Warrant Purchase Agreement dated October 21, 2020, by and between us and the holders of the warrants. Pursuant to the amendment we deferred payment of the aggregate remaining purchase price under the patent license and assignment agreement and master agreement between us and One S.r.l., totaling €2.5 million, (which we owe to One S.r.l. shareholders) until March 31, 2023.

Pursuant to the amendment, and in consideration for the deferral, we amended the exercise price of the 1,353,062 common stock warrants held by One S.r.l. shareholders from $4.26 to $1.45.

Committed Equity Facility with B. Riley Principal Capital II, LLC

On August 11, 2022, we entered into a Common Stock Purchase Agreement and a Registration Rights Agreement with B. Riley Principal Capital II, LLC ("B. Riley"). Pursuant to the agreement, we will have the right, but not the obligation, to sell to B. Riley up to the lesser of (i) $50,000,000 of newly issued shares of our common stock, and (ii) 14,506,475 shares of our common stock (which is the number of shares equal to approximately 19.99% of the aggregate number of shares of our common stock issued and outstanding immediately prior to the execution of the agreement), from time to time during the 24-month term set forth in the agreement.

Change in Management

On September 27, 2022, the Company entered into a separation and general release agreement with Mr. David Abraham, our General Counsel, Chief Compliance Officer and Corporate Secretary through September 30, 2022. Pursuant to this separation agreement, Mr. Abraham ceased serving as General Counsel, Chief Compliance Officer and Corporate Secretary, effective October 1, 2022. Mr. Abraham provided consulting services to the Company to assist with the transition of his responsibilities during the fourth quarter of 2022.

Plans to Make Plenity Available Without a Prescription

We believe Plenity's advantages are its differentiated safety-to-efficacy profile, broad approved labeling, and affordability to the consumer. Accordingly, we believe it is important that Plenity be widely available and easily accessible to consumers. In addition to making Plenity more accessible to people struggling with excess weight, we believe making Plenity available over-the-counter could reduce costs associated with acquiring new members and allow us to reduce costs associated with the prescription granting process, while also enabling new sales channels for the Company. In January 2023, we submitted a 510(k) application to the FDA to change Plenity's classification in the United States from prescription-only to OTC and expect FDA's decision on our 510(k) application by the third quarter of 2023.

Impact of COVID-19

In December 2019, illnesses associated with COVID-19 were reported and the virus has since caused widespread and significant disruption to daily life and economies across geographies. The World Health Organization has classified the outbreak as a pandemic. Our business, operations and financial condition and results have not been significantly impacted as a result of the COVID-19 pandemic, rather we recognized revenue for the first time during 2020 and we expanded our facilities, sales/marketing and supply chain personnel to support the sale of Plenity. To date, COVID-19 has not materially impacted our ability to secure and deliver supply of Plenity. To date, COVID-19 has not significantly impacted the ongoing clinical trials of our other product candidates.

In response to the COVID-19 pandemic, we have taken swift actions to ensure the safety of our employees and other stakeholders. We are diligently working with our suppliers, customers, distributors and other partners to provide consumers with access to Plenity, while taking into account regulatory, institutional, and government guidance, policies and protocols.

However, the full extent of the impact of the pandemic and future outbreaks on our business, operations, and financial condition and results in future periods remain uncertain, particularly, with respect to consumer demand for or access to Plenity, and the administration of clinical research and development activities. Further, our ability to source raw materials and components, manufacture as well as transport and distribute Plenity may be limited and therefore impact sales of Plenity.

Key Factors Affecting Results of Operations

We believe that our performance and future success depend on several factors that present not only significant opportunities for us but also pose risks and challenges, including those discussed below. In particular, our ability to successfully address the below key factors is dependent upon our ability to successfully raise the capital to fund such efforts. Our failure to obtain additional funding may force us to delay, limit or terminate our marketing efforts and investments in our product pipeline, which may negatively impact our ability to grow our business and attract and/or retain enough customers to operate profitably.

New Consumer Acquisition

Our ability to attract new consumers is a key factor for our future growth. To date we have successfully acquired consumers through our U.S. commercial launch in conjunction with the continued development of marketing and sales tactics. We intend to acquire new members in the United States by promoting Plenity directly to the consumer. In light of current cash resources, and to preserve liquidity, we reduced investments in broad awareness media and consumer acquisition, compared to prior periods. However, we continue to engage in promotional activities, which we believe will motivate a potential future member to ask a health care professional about acquiring Plenity through one of two channels:

- **Telehealth:** We partner with a leading telehealth platform in the United States, providing convenient and immediate access to physicians online at no cost. Pursuant to an amended and restatement agreement, we have granted Ro exclusive distributor rights to sell Plenity in the United States with respect to (i) consumers who seek an on-line consultation through myplenity.com in the United States and (ii) certain named competitors and or third parties.
- **Health Care Providers:** We engage a limited contract sales force to promote Plenity to target physicians. To support prescription fulfillment for our non-telehealth tradition HCP promotional efforts, we engage GoGoMeds (“GGM”), to distribute all non-telehealth mail order prescriptions generated in the United States by health care providers.

Retention of Consumers

Our ability to retain consumers is a key factor in our ability to generate revenue. We expect our direct home delivery, simple and transparent pricing, and consumer engagement to enhance the experience of our consumer and promote recurring revenue. Our customer retention efforts may be negatively impacted by recent significant reductions in our discretionary spending with respect to discretionary sales and marketing activities. If consumer retention decreases in the future, then future revenue will be negatively impacted. The ability of our consumers to continue to pay for our products and services will also impact the future results of our operations.

Rest of World

We are evaluating global strategic partnerships to build our brand globally; however, we may also retain the rights.

- **Europe:** We received approval to market Plenity in Europe through a Conformité Européenne (CE) mark for Plenity as a Class III medical device indicated for weight loss in overweight and obese adults with a Body Mass Index (BMI) of 25-40 kg/m2, when used in conjunction with diet and exercise.
- **CMS:** In Greater China (including Mainland China, Hong Kong, Macau, and Taiwan), Singapore, United Arab Emirates, Brunei, Myanmar, Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Thailand and Vietnam, we partner with China Medical System Holdings Limited (CMS) (HKG:0867) for the commercialization of Plenity.

Investments in Growth

We expect to make significant investments in selling and marketing to acquire new consumers. Selling and marketing is an important driver of growth, and over the long term, we intend to continue to make significant investments in consumer acquisition and our selling and commercial infrastructure. However, in light of current cash resources, and to preserve liquidity while we seek to raise additional capital, during the third quarter of 2022, we reduced investments in broad awareness media, consumer acquisition, and the healthcare provider sales force compared to prior periods. Accordingly, our selling and marketing expense decreased in absolute dollars during this period, which negatively impacted growth in selling Plenity. However, if we are successful in raising additional capital in the future, we expect to increase selling and marketing activities to continue to launch Plenity, and expect selling and marketing expense to decrease as a percentage of revenue over the long term, although our selling and marketing expense may fluctuate as a percentage of revenue from period to period due to the timing and amount of these expenses.

Additionally, although we intend to continue to invest in our manufacturing, fulfillment and operating capabilities in the future, these capabilities have recently been negatively impacted by recent significant reductions in our discretionary spending with respect to manufacturing and supply chain functions. If we are successful in raising additional capital in the future, we expect to continue to invest in increasing our manufacturing, fulfillment and operating capabilities. If we are unable to generate sufficient demand in Plenity, we may not have sufficient funds to invest into these growth activities.

Product Candidate Expansion

In addition to Plenity, we have invested in a pipeline of product candidates for prevalent and important gastrointestinal, or GI, tract-related chronic diseases including, type 2 diabetes, NAFLD/NASH, functional constipation, and inflammatory bowel disease by targeting the natural processes of the GI pathway. We expect to continue investing in our pipeline over time to broaden our commercial opportunity. The continued preclinical and clinical development of the pipeline will require significant financial resources. If we are unable to generate sufficient demand in Plenity or raise additional capital at favorable terms, if at all, we may not have sufficient funds to invest in the research and development of additional product candidates.

Key Business Metrics

We monitor the following key metrics to help us evaluate our business, identify trends affecting our business, formulate business plans and make strategic decisions. We believe the following metrics are useful in evaluating our business (dollar amounts in thousands except where noted):

	For the Year Ended December 31,	
	2022	2021
In thousands		
New members acquired	121,500	61,400
Units sold	374,224	170,969
Product revenue, net	$ 25,558	$ 11,185
Average selling price per unit, net	$ 68.30	$ 65.42
Gross profit	$ (2,000)	$ 1,202
Gross margin	(8)%	11%

New members acquired

We define new members acquired as the number of consumers in the United States who have begun their weight loss journey with Plenity during the financial period presented. This is the total number of recurring and non-recurring consumers who have begun their weight loss journey during the financial period presented. We do not differentiate from recurring and non-recurring consumers as of the date of this Form 10-K as (i) we strongly believe every member's weight-loss journey is chronic and long-term in nature, and (ii) we have not initiated our long-term strategy and mechanisms to retain and/or win-back members. We will continue to evaluate the utility of this business metric in future periods.

Units sold

Units sold is defined as the number of 28-day supply units of Plenity sold through our strategic partnerships with online pharmacies and telehealth providers as well as the units sold to our strategic partners outside the United States.

Product revenue, net

See discussion elsewhere in this discussion and analysis under the heading "Key Components of Results of Operations — *Product revenue, net".*

Average selling price per unit, net

Average selling price per unit, net is the gross price per unit sold during the period net of estimates of per unit variable consideration for which reserves are established for expected product returns, shipping charges to end-users, pharmacy dispensing and platform fees, merchant and processing fees, and promotional discounts offered to end-users. See "— Critical Accounting Policies and Significant Judgments and Estimates" below and the "Revenue Recognition" section of Note 2 in the accompanying Notes to unaudited consolidated financial statements included elsewhere in this Form 10-K for a more detailed discussion of our revenue recognition policy.

Gross profit and gross margin

Our gross profit represents product revenue, net, less our total cost of goods sold, including inventory reserves, and our gross margin is our gross profit expressed as a percentage of our product revenue, net. See discussion elsewhere in this discussion and analysis under the heading "Key Components of Results of Operations — *Cost of goods sold".*

Our gross profit and gross margin have been and will continue to be affected by a number of factors, including the prices we charge for our product, the costs we incur from our vendors for certain components of our cost of goods sold, the mix of channel sales in a period, and our ability to sell our inventory. We expect our gross margin to increase over the long term, although gross margins may fluctuate from period to period depending on these and other factors.

Non-GAAP Financial Measures

In addition to our financial results determined in accordance with GAAP, we believe the following non-GAAP measure is useful in evaluating our operating performance. We use the following non-GAAP financial measure to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that this non-GAAP financial measure, when taken together with the corresponding GAAP financial measure, provides meaningful supplemental information regarding our performance by excluding certain items that may not be indicative of our business, results of operations, or outlook. We consider Adjusted EBITDA to be an important measure because it helps illustrate underlying trends in our business and our historical operating performance on a more consistent basis. We believe that the use of Adjusted EBITDA is helpful to our investors as it is a metric used by management in assessing the health of our business and our operating performance.

However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. In addition, other companies, including companies in our industry, may calculate similarly-titled non-GAAP financial measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison. A reconciliation is provided below for the non-GAAP financial measure to the most directly comparable financial measure stated in accordance with GAAP. Investors are encouraged to review the related GAAP financial measure and the reconciliation of this non-GAAP financial measure to its most directly comparable GAAP financial measure, and not to rely on any single financial measure to evaluate our business.

Adjusted EBITDA

Adjusted EBITDA is a key performance measure that our management uses to assess our operating performance. Because Adjusted EBITDA facilitates internal comparisons of our historical operating performance on a more consistent basis, we use this measure for business planning purposes. We define "Adjusted EBITDA" as net (loss) income before depreciation and amortization expenses, provision for (benefit from) income taxes, interest expense, net, stock-based compensation and (gains) and losses related to changes in fair value of our earnout liability, fair value of our warrant liability, our convertible promissory note liability and the One S.r.l. call option.

The following table reconciles net loss to Adjusted EBITDA for the years ended December 31, 2022 and 2021, respectively:

In thousands	For the Year Ended December 31, 2022	2021
Adjusted EBITDA		
Net loss	$ (55,780)	$ (93,347)
Provision for income taxes	480	17
Depreciation and amortization	5,488	3,791
Stock based compensation expense	29,777	5,532
Change in fair value of earnout liability	(58,308)	—
Change in fair value of warrants	(7,084)	7,646
Change in fair value of convertible promissory notes	2,559	128
Change in fair value of One S.r.l. call option	(1,462)	1,024
Interest expense, net	991	1,364
Adjusted EBITDA	$ (83,339)	$ (73,845)

Some of the limitations of Adjusted EBITDA include (i) Adjusted EBITDA does not properly reflect capital commitments to be paid in the future, and (ii) although depreciation and amortization are non-cash charges, the underlying assets may need to be replaced and Adjusted EBITDA does not reflect these capital expenditures. In evaluating Adjusted EBITDA, you should be aware that in the future we will incur expenses similar to the adjustments in this presentation. Our presentation of Adjusted EBITDA should not be construed as an inference that our future results will be unaffected by these expenses or any unusual or non-recurring items. When evaluating our performance, you should consider Adjusted EBITDA alongside other financial performance measures, including our net loss and other GAAP results.

Basis of Presentation

Our consolidated financial statements and consolidated financial statements are prepared in accordance with GAAP. Any reference in this discussion and analysis to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") issued by the Financial Accounting Standards Board ("FASB").

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, the Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. We view our operations and manage our business as one operating segment.

The noncontrolling interest attributable to Gelesis S.r.l., our variable interest entity ("VIE"), is presented as a separate component from stockholders' deficit in our consolidated balance sheets and as a noncontrolling interest in our consolidated statements of noncontrolling interest, redeemable convertible preferred stock and stockholders' deficit. All intercompany balances and transactions have been eliminated in consolidation.

Key Components of Results of Operations

Product revenue, net

We recognize product revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, when we transfer promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

Our product revenue is derived from product sales of Plenity, net of estimates of variable consideration for which reserves are established for expected product returns, shipping charges to end-users, pharmacy dispensing and platform fees, merchant and processing fees, and promotional discounts offered to end-users.

Cost of goods sold

Cost of goods sold includes the cost of manufacturing our proprietary superabsorbent hydrogels for Plenity for which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management and quality assurance, and inventory reserves. Expenses from royalty agreements on net product sales are also recognized as a component of cost

of goods sold during the period in which the associated revenues are recognized. A portion of depreciation with respect to property and equipment directly utilized in manufacturing Plenity units is recognized as a component of cost of goods sold over the depreciable life of the asset.

Selling, general and administrative expense

A significant component of our selling, general and administrative expenses is comprised of our selling and marketing expense, which includes our limited contract sales force in the US markets and discretionary consumer acquisition expenses.

Selling, general and administrative costs are expensed as incurred. Selling, general and administrative costs include sales and marketing costs incurred as a result of the commercialization of our products, payroll and personnel expense, stock-based compensation expense, and costs of programs and infrastructure necessary for the general conduct of our business.

Research and development expense

Research and development costs are expensed as incurred. Prepaid research and development costs are deferred and amortized over the service period, as the services are provided. Research and development costs include payroll and personnel expense, stock-based compensation expense, consulting costs, external contract research and development expenses, as well as depreciation and utilities. These activities relate primarily to formulation, CMC, preclinical and discovery activities. As such, we do not track these research and development expenses on an indication-by-indication basis as they primarily relate to expenses which are deployed across multiple projects under development or are for future product and pipeline candidates which utilize our platform technology.

Clinical trial costs are a component of research and development expenses and consist of clinical trial and related clinical manufacturing costs, fees paid to clinical research organizations and investigative sites. We track and maintain these costs on an indication-by-indication basis.

Amortization expense

Amortization expense relates to the intangible asset that resulted from an amendment to our master agreement with the original inventor of our core patents, pursuant to which the percentage of royalties we are required to pay on future net revenues was reduced. The intangible asset is amortized over its useful life, which was determined as of the date of the amendment to be the earliest expiration of patents related to the underlying IP in November 2028.

Other non-operating income (expense), net

Change in the fair value of earnout liability

We have earnout shares which are contingent issuable as incremental consideration pursuant to ASC 815. The earnout shares are initially recorded at fair value and remeasured to fair value at each reporting date until settlement with gains and losses arising from changes in fair value recognized in the consolidated statements of operations.

Changes in the fair value of warrants

We have issued warrants to investors which are liability classified and initially recorded at fair value and remeasured to fair value at each reporting date until settlement with gains and losses arising from changes in fair value recognized in the consolidated statements of operations.

Change in the fair value of convertible promissory notes

We have issued convertible promissory notes to investors which are initially recorded at fair value and remeasured to fair value at each reporting date until repayment or conversion at the option of the holders, with gains and losses arising from changes in fair value recognized in the consolidated statements of operations.

Interest expense, net

Interest expense, net consists of interest incurred on our various loans and interest income earned on our cash, cash equivalents and marketable securities.

Other income (expense), net

Other income, net primarily consists of income earned on our grants from government agencies in Italy, research and development tax credits earned in Italy for qualifying expenses, and gains and losses on foreign currency transactions. Other income, net also consists of changes in fair value of the One S.r.l. call option.

Provision for income taxes

We must make certain estimates and judgments in determining income tax expense for financial statement purposes. The amount of taxes currently payable or refundable is accrued, and deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amount of existing assets and liabilities and their respective tax bases. Deferred tax assets are also recognized for realizable loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using substantively enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. Net deferred tax assets are not recorded if we do not assess their realization as probable. The effect on deferred tax assets and liabilities of a change in income tax rates is recognized in our financial statements in the period that includes the substantive enactment date.

Results of Operations

Comparison of the years ended December 31, 2022 and 2021:

	For the Year Ended December 31,		
	2022	2021	Change
Revenue:			
Product revenue, net	$ 25,558	$ 11,185	$ 14,373
Licensing revenue	209	—	209
Total revenue, net	25,767	11,185	14,582
Operating expenses:			
Costs of goods sold	27,558	9,983	17,575
Selling, general and administrative	99,135	71,041	28,094
Research and development	18,613	12,867	5,746
Amortization of intangible assets	2,267	2,267	—
Total operating expenses	147,573	96,158	51,415
Loss from operations	(121,806)	(84,973)	(36,833)
Other non-operating income (expense), net	66,506	(8,357)	74,863
Loss before income taxes	(55,300)	(93,330)	38,030
Provision for income taxes	480	17	463
Net loss	$ (55,780)	$ (93,347)	$ 37,567

Product revenue, net

We recognized product revenue, net of $25.6 million and $11.2 million for the years ended December 31, 2022 and 2021, respectively, an increase of $14.4 million or 129%. We sold 374,224 units at an average selling price per unit, net of $68.30 for the year ended December 31, 2022, as compared to 174,425 units at an average selling price per unit, net of $64.12 for the year ended December 31, 2021.

The increase in units sold was primarily attributable to the execution of our commercialization strategy and ramp up between 2021 and 2022. We made Plenity available for commercial sale through a beta launch that began in October 2020 and continued throughout 2021. Activities associated with a full commercial launch of the Product in the United States began in late 2021, and in February 2022, we launched the first national broad awareness media campaign for Plenity and invested in building broad awareness during the year ended December 31, 2022. However, in light of available cash resources, during the third quarter of 2022, we reduced investments in broad awareness media and consumer acquisition compared to previous quarters in 2022 and 2021, which negatively impacted growth in selling Plenity.

Cost of goods sold

We recognized cost of goods sold of $27.6 million and $10.0 million for the years ended December 31, 2022 and 2021, respectively, an increase of $17.6 million or 176%. Increase in cost of goods sold was primarily driven by the establishment of inventory reserve of

$13.3 million during the year ended December 31, 2022, driven by reduced demand for Plenity in light of our reduced investments in selling and marketing activities during the second half of 2022, and pending application with the FDA to change the classification of Plenity to OTC. Additional increases in cost of goods sold were driven by the increase in units sold, partially offset by a lower cost per unit for the year ended December 31, 2022, as compared to the year ended December 31, 2021. Depreciation recognized as a component of cost of goods sold was $1.8 million and $1.0 million for the years ended December 31, 2022 and 2021, respectively.

We recognized a gross loss of $2.0 million and a gross profit of $1.2 million for the years ended December 31, 2022 and 2021, respectively, a decrease of $3.2 million. Gross margin was -8% for the year ended December 31, 2022, as compared to 11% for the year ended December 31, 2021. We achieved a lower cost of goods per unit after our first commercial-scale manufacturing facility commenced manufacturing in the fourth quarter of 2021, however the negative gross margin during the year ended December 31, 2022, was attributable to the establishment of an inventory reserve of $13.3 million.

Selling, general and administrative expense

The following table summarizes our selling, general and administrative expenses for the years ended December 31, 2022 and 2021:

	For the Year Ended December 31,		
	2022	2021	Change
In thousands			
Selling and marketing expense	$ 56,924	$ 52,781	$ 4,143
General and administrative expense	22,132	14,293	7,839
Non-cash stock-based compensation expense	20,079	3,967	16,112
Total selling, general and administrative expense	$ 99,135	$ 71,041	$ 28,094

Total selling, general and administrative expense was $99.1 million and $71.0 million for the years ended December 31, 2022 and 2021, respectively, an increase of $28.1 million or 40%.

Selling and marketing expense increased $4.1 million for the year ended December 31, 2022, as compared to the year ended December 31, 2021. The increase in selling and marketing expense was primarily attributable to increased marketing spend to support the commercial sale of Plenity. In February 2022, we launched the first national broad awareness media campaign for the product, which included TV, digital, social, and Out of Home media channels to grow awareness of Plenity. We continued to invest in broad awareness during the year ended December 31, 2022, though primarily in the first and second quarter of 2022.

General and administrative expense increased $7.8 million for the year ended December 31, 2022, as compared to the year ended December 31, 2021. The increase was primarily attributable to professional and legal expenses incurred post the Business Combination, as well as directors and officers insurance and other related costs as a public company.

Non-cash stock-based compensation expense increased $16.1 million for the year ended December 31, 2022, as compared to the year ended December 31, 2021. The increase was primarily attributable to compensation cost with respect to the issuance of new equity awards in 2022 as well as the incremental compensation cost with respect to contingently issuable earnout shares pertaining to Legacy Gelesis equity awards.

Research and development expenses

The following table summarizes our research and development expenses for the years ended December 31, 2022 and 2021:

	For the Year Ended December 31,		
	2022	2021	Change
In thousands			
GS200	$ 66	$ —	$ 66
GS300	133	1,467	(1,334)
GS500	79	1,636	(1,557)
Unallocated expenses			
Other research and development expenses	8,637	8,199	438
Non-cash stock-based compensation expense	9,698	1,565	8,133
Total Research and development expense	$ 18,613	$ 12,867	$ 5,746

Total research and development expense was $18.6 million and $12.9 million for the years ended December 31, 2022 and 2021, respectively, an increase of $5.7 million or 45%.

Non-cash stock-based compensation expense increased $8.1 million for the year ended December 31, 2022, as compared to the year ended December 31, 2021. The increase was primarily attributable to compensation cost with respect to the issuance of new equity awards in 2022 as well as the incremental compensation cost with respect to contingently issuable earnout shares pertaining to Legacy Gelesis equity awards.

The decrease in research and development expenses within clinical indications (GS200, GS300 and GS500) was primarily attributable to the conclusion of the LIGHT-UP study with respect to GS200 during the year ended December 31, 2021, as well as the strategic prioritization of the commercialization of Plenity particularly with respect to our financial and human resources.

Other non-operating income (expense), net

The following table summarizes our other non-operating income and expenses for the years ended December 31, 2022 and 2021:

	For the Year Ended December 31,		
	2022	2021	Change
In thousands			
Change in the fair value of earnout liability	$ 58,308	$ —	$ 58,308
Change in the fair value of convertible promissory notes	(2,559)	(128)	(2,431)
Change in the fair value of warrants	7,084	(7,646)	14,730
Interest expense, net	(991)	(1,364)	373
Other income, net	4,664	781	3,883
Total non-operating expenses, net	$ 66,506	$ (8,357)	$ 74,863

We recognized other non-operating income, net of $66.5 million for the year ended December 31, 2022, as compared to expense, net of $8.4 million for the year ended December 31, 2021, an increase in income of $74.9 million. The income for the year ended December 31, 2022 was primarily attributable to income of $58.3 million with respect to the change in fair value of our earnout liability, income of $14.7 million with respect to the change in fair value of our warrant liabilities as well as income of $1.5 million with respect to the One S.r.l. call option. The income for the year ended December 31, 2022 was further attributable to $0.8 million in investment tax credit income recognized with respect to certain tax incentives offered for property and equipment investment in Italy and income of $1.9 million recognized with respect to grants awarded by the Puglia region of Italy.

The $8.4 million non-operating expense for the year ended December 31, 2021 was primarily attributable to a loss of $7.6 million with respect to the change in fair value of our warrant liabilities, interest expense of $1.4 million and One S.r.l call option fair value change of $1.0 million, partially offset by income of $1.6 million recognized with respect to grants awarded by the Puglia region of Italy.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily from the issuance of equity and debt instruments, license and collaboration agreements, supply and distribution agreements, and government grants. As of December 31, 2022, our principal sources of liquidity were our cash and cash equivalents in the amount of $24.8 million. During the year ended December 31, 2022, we closed a business combination with CPSR, pursuant to which we received $105.0 million in gross proceeds, prior to the payment of transaction fees due and payable. As of the date of this Form 10-K, we expect that our existing cash and cash equivalents, proceeds from the initial closing of the 2023 Convertible Senior Secured Notes, and collection of accounts and grants receivable will only be sufficient to fund our operating expenses and capital expenditure requirements into the early second quarter of 2023.

Due to our available cash and cash equivalents, a history of recurring losses from operations, negative cash flows from operations, and a significant accumulated deficit, we have concluded that there is substantial doubt about our ability to continue as a going concern. In addition, our independent registered public accounting firm included an emphasis of matter paragraph in their opinion for the years ended December 31, 2022 and 2021, respectively, as to the substantial doubt about our ability to continue as a going concern. Our unaudited consolidated financial statements included elsewhere in this Form 10-K, which have been prepared in accordance with GAAP, contemplate that we will continue to operate as a going concern. Our financial statements do not contain any adjustments that might result if we are unable to continue as a going concern.

We have incurred negative cash flows from operating activities and significant losses from operations in the past. We expect to continue to incur operating losses for at least the next twelve months due to the investments that we intend to make in our business to support the commercialization of Plenity and, as a result, we will require additional capital resources to grow our business.

Future Liquidity Requirements

Due to limited available liquidity to fund operations, we implemented an alternative business plan, significantly curtailed our sales marketing as well as supply chain activities since the third and fourth quarter of 2022, reduced headcount and delayed certain long-term capital expenditures in commercial infrastructure and certain research and development expenses. We have sought out, and continue to seek out, financing and other alternative commercial arrangements or geographic distribution partnerships to finance certain investments in sales and marketing associated with the sale of Plenity. We expect these actions will provide us with sufficient liquidity to manage short-term risk and uncertainty and (i) enable us to execute our alternative business plan, (ii) afford us time to access financing alternatives to provide for long-term liquidity and (iii) enable us to fund the continued commercialization of Plenity. See Part I, Item 1A, "Risk Factors — If we are not successful in implementing an alternative business plan and/or raising additional capital in a timely manner, we may have insufficient cash and liquidity to pay operating expenses and other obligations. Any such event would have a material adverse effect on our business and financial condition." and "Risk Factors — Risks Related to Financial Position and Financing Needs — In order to support our business, we will need to incur additional indebtedness or seek capital through new equity or debt financings, which sources of additional indebtedness or capital have become increasingly difficult to secure and may not be available on acceptable terms, if at all, and the failure to obtain this additional funding when needed may force us to delay, limit or terminate our product development efforts or other operations." in this Form 10-K for more information regarding certain factors that may impact our liquidity and our ability to raise additional capital.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through issuance of additional equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions.

As of the date of this Form 10-K, we are continuing to evaluate opportunities to raise additional capital. If we are unsuccessful in raising additional capital, we may need to further restrict our spending particularly with respect to discretionary sales and marketing activities and our manufacturing and supply chain functions, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code. Further changes to the execution of our alternative business plan may impact the growth of Plenity sales and the pace of acquisition and retention of consumers, as well as the price of our common stock.

Revenue Projections

Our revenue projections are highly dependent on (i) our ability to acquire new consumers and/or retain existing consumers and (ii) our ability to access additional capital and raise sufficient levels of funding in a timely manner to support the sales and marketing of Plenity at a broad national level within the United States. If our access to additional capital is delayed or insufficient, it may adversely impact the sale of Plenity and our revenue projections. See Part I, Item 1A "Risk Factors – Risks Related to Financial Position and Financing Needs – The financial and operational projections and commercialization and product candidate development timelines that we may provide from time to time are subject to inherent risks." in this Form 10-K for more information.

Warrant Proceeds

As of the date of this Form 10-K, we have (i) 13,800,000 outstanding Public Warrants to purchase 13,800,000 shares of our common stock, exercisable at an exercise price of $11.50 per share, which expire on the earlier to occur of January 13, 2027 or redemption; (ii) 7,520,000 outstanding Private Warrants to purchase 7,520,000 shares of our common stock, exercisable at an exercise price of $11.50 per share, which expire on the earlier of January 13, 2027 or redemption; (iii) 3,013,365 exercisable Rollover Warrants, 1,353,062 of which are exercisable at an exercise price of $4.26 and expire on October 21, 2030 and 1,660,303 of which are exercisable at an exercise price of $0.02 and expire on February 15, 2025; (iv) 400,000 warrants issued to CMS which are exercisable at an exercise price of $0.01 and expire on August 4, 2032; and (v) 23,688,047 warrants issued in connection with the Note and Warrant Purchase Agreement with PureTech Health LLC at an exercise price of $0.2744 and expire no sooner than February 21, 2038.

The exercise of warrants is highly dependent on the price of our common stock and the spread between the exercise price of the warrant and the price of our common stock at the time of exercise. For example, to the extent that the price of our common stock exceeds $11.50 per share, it is more likely that holders of our Public Warrants and Private Warrants will exercise their warrants. To the extent that the price of our common stock is less than $11.50 per share, it is less likely that such holders will exercise their warrants. In January 2023, the NYSE delisted our Public Warrants as the trading price fell below $0.01. As of March 24, 2023, the closing price of our common stock price was $0.17 per share. There can be no assurance that our warrants will be in the money prior to their expiration and, as such, any or all of our warrants may expire worthless. Our Public Warrants under certain conditions, as described in the warrant agreement, are redeemable by the Company at a price of $0.01 per warrant or on a cashless basis. Our Private

Warrants are not redeemable so long as they are held by the initial stockholders and are exercisable on a cashless basis. Our CMS Warrants and PureTech Health LLC Warrants are not redeemable and are exercisable on a cashless basis, and our Rollover Warrants are not redeemable and have an exercise price of $0.02. As such, it is possible that we may never generate any significant cash proceeds from the exercise of our warrants. As of the date of this Form 10-K, we have neither included nor intend to include any potential cash proceeds from the exercise of our warrants in our short-term or long-term liquidity projections. We will continue to evaluate the probability of warrant exercise over the life of our warrants and the merit of including potential cash proceeds from the exercise thereof in our liquidity projections.

To the extent such warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to the holders of our common stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of our common stock, which increase the likelihood that our warrants will not be in the money prior to their expiration.

Financing Risk

We expect to devote significant efforts to raise capital, restructure our indebtedness and identify and evaluate potential strategic alternatives, however, there can be no assurance that we will be successful in obtaining capital sufficient to meet our operating needs on terms or a timeframe acceptable to us or at all. Further, in the event that market conditions preclude our ability to consummate such a transaction, we may be required to evaluate additional alternatives in restructuring our business and our capital structure. Any failure in these efforts could force us to delay, limit or terminate our operations, make reductions in our workforce, discontinue our commercialization efforts for Plenity as well as other development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

Although we have estimated our liquidity requirements based on assumptions that we consider to be reasonable, we may need additional cash resources due to changed business conditions or other developments, including supply chain challenges, disruptions due to COVID-19, competitive pressures, inflationary pressures and regulatory developments, among other developments. Our budget projections may be subject to cost overruns for reasons outside of our control and Plenity may experience slower sales growth than anticipated, which would pose a risk to achieve positive cash flow.

Our future capital requirements will depend on many factors, including increases in sales of Plenity, increases in our customer base, the timing and extent of spend to support the expansion of sales, marketing and development activities, and the impact of the COVID-19 pandemic. We may in the future also enter into arrangements to acquire or invest in complementary businesses, services and technologies, including intellectual property rights.

We have based our estimate of liquidity on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our cash flows may fluctuate and are difficult to forecast and will depend on many factors mentioned elsewhere in this discussion and analysis. If we require additional equity or debt financing from outside sources, we may not be able to raise it on terms acceptable to us, or at all, and may pursue financing transactions that will not be completed. If we are unable to raise additional capital when desired, our business, financial condition and results of operations would be harmed.

Cash flows

The following table summarizes our cash flows for each of the periods presented:

	For the Year Ended December 31,	
	2022	2021
In thousands		
Cash (used in) provided by:		
Operating activities	$ (77,728)	$ (55,291)
Investing activities	(9,120)	4,083
Financing activities	66,325	32,533
Effect of exchange rates on cash	(462)	(1,072)
Decrease in cash and cash equivalents	$ (20,985)	$ (19,747)

Cash used in operating activities

Net cash used in operating activities was $77.7 million and $55.3 million for the years ended December 31, 2022 and 2021, respectively. Our net loss after adjusting for non-cash operating activities was $70.5 million for the year ended December 31, 2022, as

compared to $74.5 million for the year ended December 31, 2021, a decrease in loss after adjusting for non-cash operating activities of $3.4 million. We received $15.0 million and $40.0 million pre-buy commitments from Ro during the years ended December 31, 2022 and 2021, respectively. Net cash used in operating activities was further influenced by the timing of receivables from our government grants as well as GGM during the years ended December 31, 2022 and 2021.

Cash (used in) provided by investing activities

Net cash used in investing activities was $9.1 million for the year ended December 31, 2022, as compared to $4.1 million provided by investing activities for the year ended December 31, 2021. The outflows were primarily attributable to $8.5 million in the purchase of property and equipment for the year ended December 31, 2022. For the year ended December 31, 2021, inflows were primarily attributable to $24.0 million in maturities of marketable securities, which were partially offset by $19.9 million in the purchase of property and equipment for the year ended December 31, 2021.

Cash provided by financing activities

Net cash provided by financing activities was $66.3 million and $32.5 million for the years ended December 31, 2022 and 2021, respectively. The increase in inflows was primarily attributable to net proceeds of $70.5 million received from the completion of the Business Combination in January 2022 and $25 million proceeds from issuance of promissory notes, partially offset by our repayment of convertible promissory notes also in January 2022, totaling $27.3 million, as compared to $27 million proceeds from issuance of convertible promissory notes and $5.7 million proceeds from issuance of loans in Italy for the year ended December 31, 2021.

Contractual Obligations and Commitments

Our contractual obligations primarily consist of our commitments under non-cancellable operating leases, promissory notes and debt obligations as well as contractual obligations under significant agreements with related and unrelated parties.

For the year ended December 31, 2022, we issued three term promissory notes in the aggregate principal amount of $25.0 million to existing investor CMS, and existing investors and related parties PureTech Health LLC and SSD2 LLC, for an aggregate cash purchase price of $25.0 million. Each of the promissory notes is unsecured and bears interest at a rate of 15% per annum. Each promissory note matures on the earlier of (a) December 31, 2023 or (b) five (5) business days following a qualified financing. Upon a payment default under any promissory note that has not been cured after five days (i) the Company will be required to issue certain warrants to the holders as defined by the promissory note agreements and (ii) the holders will have the option to convert outstanding principal and accrued interest into a number of shares of Gelesis common stock as defined by the promissory note agreements.

At December 31, 2022, the aggregate outstanding balance of the promissory notes was $27.4 million recorded at fair value in the accompanying consolidated balance sheets. We recognized a loss of $2.4 million with respect to the change in the fair value of the 2022 Promissory Notes.

See also Note 12. Debt in the accompanying Notes to the consolidated financial statements included elsewhere in this Form 10-K for a description of the Company's debt outstanding and the terms of its debt facilities for the years ended December 31, 2022 and December 31, 2021.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results may differ from management's estimates. To the extent that there are material differences between these estimates and actual results, our consolidated financial statements will be affected. On an ongoing basis, we evaluate our estimates, judgements, and assumptions. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 2 - Summary of Significant Accounting Policies to the consolidated financial statements included in Part II, Item 8 of this Form 10-K. These are the policies that we believe are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of operations.

Inventory

We manufacture our own super-absorbent hydrogels used in Plenity® and other product candidates out of its own manufacturing facilities located in Italy. The packaging of the hydrogels is currently outsourced to contract packaging organizations for commercial purposes.

Inventories comprise raw materials, including raw materials for packaging components, work-in-process, and finished goods, which are goods that are available for sale. We state inventory at the lower of cost or net realizable value with the cost based on the first-in, first-out method. If we identify excess, obsolete or unsalable items, we write down related inventory to its net realizable value in the period in which the impairment is identified. These adjustments are recorded based upon various factors related to the product, including the level of product manufactured by us, the level of product in the distribution channel, current and projected demand, the expected shelf-life of the product and firm inventory purchase commitments. Significant shipping and handling costs incurred for inventory purchases are included in inventory and costs incurred for product shipments are recorded in cost of goods sold as incurred.

Intangible Assets

Intangible assets with estimable useful lives, or definite-lived intangibles, are carried at cost and are amortized on a straight-line basis over their estimated useful lives and reviewed for impairment upon certain triggering events. We routinely review the remaining estimated useful lives of definite-lived intangible assets. If we reduce the estimated useful life assumption, the remaining unamortized balance is amortized over the revised estimated useful life.

Noncontrolling Interests

We recognize noncontrolling interest related to VIEs, in which the Company is the primary beneficiary, as temporary equity in the consolidated financial statements separate from the shareholders' equity. Changes in the shareholders' ownership interest in a subsidiary that do not result in deconsolidation are treated as equity transactions if the parent entity retains its controlling financial interest. In addition, when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary will be initially measured at fair value and the difference between the carrying value and fair value of the retained interest will be recorded as a gain or loss.

Product Revenue

We commercialize Plenity in the U.S. markets principally through synergistic partnerships with online pharmacies and telehealth providers, which in turn sell Plenity directly to patients based on prescriptions. Outside the U.S., the Company primarily seeks collaborations with strategic partners to market Plenity and obtain necessary regulatory approvals as necessary.

Product revenue is recognized by us in an amount that reflects the consideration which we expect to receive in exchange for those goods or services when the customer obtains control of the product, which occurs at a point in time, when the product is received by our customers.

Stock-Based Compensation

The Company's stock-based compensation consist primarily of stock options and restricted stock units. The measurement date for share-based awards is the date of grant, and stock-based compensation costs are recognized as expense over the respective requisite service periods, which are typically the vesting period. The fair value of each stock option grant is estimated as of the date of grant using the Black-Scholes option-pricing model that requires management to apply judgment and make estimates, including:

- *exercise price:* The exercise price is the fair market value on grant date, which shall mean the closing sale price of common stock, as reported on such market on that date (or if there are no market quotations for such date, the determination shall be made by reference to the last date preceding such date for which there are market quotations);
- *expected volatility:* As the Company was previously a privately-owned company, there is not sufficient historical volatility for the expected term of the options. Therefore, the Company used an average historical share price volatility based on an analysis of reported data for a peer group of comparable companies for which historical information is available. For these analyses, the Company selects companies with comparable characteristics to itself including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of its stock-based awards. The Company intends to consistently apply this process using representative companies until a sufficient amount of historical information regarding the volatility of its own share price becomes available;
- risk-free interest rate, which is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption;
- expected term, which is calculated using the simplified method, as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment,* as the Company has insufficient historical information regarding its stock options to provide a basis for an estimate. Under this approach, the weighted-average expected life is

presumed to be the average of the contractual term of ten years and the weighted-average vesting term of the stock options, taking into consideration multiple vesting tranches;

- dividend yield, which is zero based on the fact that the Company never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Stock-based compensation costs for non-employees are recognized as expense over the vesting period. Stock-based compensation expense is classified in the consolidated statements of operations based on the function to which the related services are provided. Forfeitures are recorded as they occur.

Business Combination and Reverse Recapitalization

We accounted for our January 2022 Business Combination as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, CPSR, who was the legal acquirer, was treated as the acquired company for financial reporting purposes. Accordingly, the Business Combination was treated as the equivalent of Gelesis issuing stock for the net assets of CPSR, accompanied by a recapitalization.

JOBS Act Accounting Election

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, an "emerging growth company" can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have elected to avail ourselves of this exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies. However, where allowable we have early adopted certain standards as described in Note 2 of our consolidated financial statements. There are other exemptions and reduced reporting requirements provided by the JOBS Act that we are currently evaluating. For example, as an "emerging growth company," we are exempt from Sections 14A(a) and (b) of the Exchange Act which would otherwise require us to (1) submit certain executive compensation matters to shareholder advisory votes, such as "say-on-pay," "say-on-frequency," and "golden parachutes;" and (2) disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of our chief executive officer's compensation to our median employee compensation.

We also intend to rely on an exemption from the rule requiring us to provide an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We will continue to remain an "emerging growth company" until the earliest of the following: (1) the last day of the fiscal year following the fifth anniversary of our initial public offering; (2) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.07 billion; (3) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

This information appears following Item 15 of this Form 10-K and is included herein by reference.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, who serve as our principal executive officer and principal financial officer, respectively, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive officer and principal financial officer, or persons performing similar functions, and effected by a company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of a company's assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that a company's receipts and expenditures are being made only in accordance with authorizations of the company's management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.
Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022 based on the criteria set forth by the

Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 framework). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2022.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to our status as an emerging growth company under the JOBS Act.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Board of Directors and Management

The following sets forth certain information, as of March 23, 2023, concerning our directors and executive officers.

Name	Age	Title
Yishai Zohar	60	President, Chief Executive Officer, Class III Director and Co-Inventor
David Pass, Pharm.D.	55	Chief Operating Officer and Chief Commercial Officer
Elliot Maltz, CPA	38	Chief Financial Officer, Treasurer, Chief Compliance Officer and Corporate Secretary
Alessandro Sannino, Ph.D.	51	Co-Inventor & Lead Project Scientist
Alison Bauerlein*(1)	41	Class I Director
Dominic Perks*(1)	46	Class I Director
Kathryn Cavanaugh*(2)	49	Class II Director
Clayton Christopher*(3)	50	Class II Director
Paul Fonteyne*(3)	61	Class II Director
Raju Kucherlapati, Ph.D.*(1)(2)	80	Class III Director
Jane Wildman*(2)	62	Class III Director

* Indicates non-employee director.

(1) Audit Committee Member.

(2) Compensation Committee Member.

(3) Nominating and Corporate Governance Committee Member.

Executive Officers and Significant Consultants

Yishai Zohar has served as our President and Chief Executive Officer and as a member of our Board since January 2022. Mr. Zohar is the Founder of Gelesis, Inc. and previously served as the Chief Executive Officer and a member of the Gelesis, Inc. board of directors from February 2006 to January 2022. He is a seasoned entrepreneur and has over 25 years' experience in the development of industry innovating companies. Mr. Zohar led Gelesis from concept stage and initial product development as a Co-Inventor and shepherded the company and its novel technological platform through clinical studies and a landmark FDA clearance of lead product Plenity as an aid for weight management. Prior to founding Gelesis, Inc., Mr. Zohar co-founded PureTech Health (NASDAQ, LSE: PRTC), a biotherapeutics company dedicated to discovering, developing and commercializing highly differentiated medicines to impact human health. In his role at PureTech, Mr. Zohar led the obesity/gastrointestinal disorder initiative, which engaged leading experts to tackle these problems with an unbiased discovery process looking at a broad landscape of technologies and approaches. This initiative led to the formation of Gelesis, Inc. Mr. Zohar has a degree in Business Administration from the College of Management Academic Studies (COMAS) in Tel Aviv and was an air force pilot ranked Captain in the Israeli Defense Forces. We believe that Mr. Zohar's qualifications to serve on our Board include his extensive experience and track record in the development of industry innovative companies.

David Pass, Pharm.D., has served as our Chief Operating Officer and Chief Commercial Officer since January 2022. Dr. Pass has previously served as the Gelesis, Inc. Chief Operating Officer and Chief Commercial Officer from September 2016 to January 2022 and has more than 25 years of commercial expertise across multiple therapeutic areas with a focus in primary care. Dr. Pass gained a broad range of commercial experience from his time at Johnson & Johnson from August 2002 to January 2008 where he served as VP of Marketing, and at Bristol-Myers Squibb from May 1994 to July 2002, where he served as Director of Marketing. Most recently, Dr. Pass served as Vice President of Marketing at Boehringer Ingelheim, or BI, for Diabetes from August 2009 to August 2016, where he built a multi-billion dollar franchise. In this role, Dr. Pass also led the BI alliance with Eli Lilly & Company to develop and commercialize a portfolio of diabetes compounds. Dr. Pass received his B.S. Pharmacy and Doctor of Pharmacy degrees from Philadelphia College of Pharmacy and Science.

Elliot Maltz, CPA, has served as our Chief Financial Officer and Treasurer since January 2022, and as our Chief Compliance Officer and Corporate Secretary since October 2022. Mr. Maltz previously served as the Gelesis, Inc. Chief Financial Officer from May 2021 to January 2022 and as its Treasurer from May 2015 to January 2022. Prior to his appointment as the CFO of Gelesis, Inc., Mr. Maltz was Gelesis, Inc.'s Vice President of Finance and previously served as its Corporate Controller. Mr. Maltz has 15 years of accounting and corporate finance experience working with public and private companies, specializing in the biotechnology, medical device and

manufacturing industries. Prior to joining Gelesis, Inc., Mr. Maltz served as an external auditor at Deloitte & Touche LLP from January 2007 to April 2013 and as a manager of the technical accounting and SEC reporting function at Sapient Corp. from April 2013 to March 2014. Mr. Maltz received a B.S. in Business Finance from Elon University and is a licensed CPA in the state of Massachusetts.

Alessandro Sannino, Ph.D., has served as our Lead Project Scientist since January 2022. Dr. Sannino is a Gelesis Co-Inventor and previously served as the Lead Project Scientist for Gelesis, Inc. from May 2008 to January 2022. Dr. Sannino has been a Professor of Polymer Science and Technology and the director of the Bioslabs at the University of Salento since September 2000. Since March 2012, Dr. Sannino has overseen the Life Science division of the Puglia District of Technology and since September 2004, he has been a member of the adjunct faculty at the Massachusetts Institute of Technology (MIT). Dr. Sannino also served as an advisor to the National Institute of Health, of the Italian Ministry of Health (the Italian equivalent to the U.S. FDA). Since 2013, he has been a board member of the European Laboratory of non-linear Spectroscopy and of the Regional Agency for Research and Innovation. Since September 2019, he has been Vice Dean of the University of Salento and since May 2020 he has been nominated by the President of Puglia Region as one of the seven (7) experts for the recovery after the COVID-19 pandemic. Dr. Sannino's research activity is focused on macromolecular hydrogels, polymer microstructure modifications, tissue engineering constructs and cell-material interactions, and he has published over 130 scientific papers on these topics. Dr. Sannino received his PhD at University of Naples, and he also completed a post-doctoral fellowship at MIT.

Non-Employee Directors

Alison Bauerlein has served as a member of our Board since January 2022. Ms. Bauerlein was a co-founder of Inogen, Inc. and served as its Chief Financial Officer from 2009 until December 2021 and its Executive Vice President, Finance from March 2014 until December 2021. Ms. Bauerlein has also served as Inogen's Corporate Secretary from 2002 until July 2021 and its Corporate Treasurer from 2002 until December 2021. Ms. Bauerlein previously served as Inogen Inc.'s Vice President, Finance from 2009 until March 2014. Prior to serving in these positions, Ms. Bauerlein also served as Controller with Inogen, Inc. from 2008 to 2009 and 2001 to 2004, and the Director of Financial Planning and Analysis from 2004 to 2008. Ms. Bauerlein has also been a board member of Pear Therapeutics, Inc. since December 2021. Ms. Bauerlein has over 20 years of experience in treasury, finance, accounting, risk management as well as strategic and tactical cost analysis and forecasting. Ms. Bauerlein received a Bachelor of Arts degree in Economics/ Mathematics with high honors from the University of California, Santa Barbara. We believe Ms. Bauerlein's qualifications to serve on our Board include her extensive executive-level experience in the medical technology industry, as well as her financial expertise.

Dominic Perks has served as a member of our Board since January 2022 and has previously served as a member of the Gelesis, Inc. board of directors from April 2021 to January 2022. In October 2013, Mr. Perks co-founded Hambro Perks with British banker and businessman Rupert Hambro. In 2014, Mr. Perks co-founded Laundrapp, an on-demand dry cleaning and laundry service and served as chairman until November 2018. Mr. Perks has since founded or seeded numerous technology companies including Echo, What3Words, By Miles, Primary Bid, Takumi and Insurtech Gateway. Through Hambro Perks, he is an investor in over 95 companies including Cambridge Innovation Capital, Tide and Muzmatch. In December 2020, Mr. Perks led the acquisition of Ombu Group in partnership with Sir John Rose and created Hambro Perks Environmental Technology Fund. Mr. Perks also acquired all of Invesco's unquoted assets in the UK and US in a deal that included stakes in Gelesis, Inc., Vedanta, Genomics, Nexeon and Hawkeye360. In February 2021, Mr. Perks launched the Hambro Perks Oryx Fund with backing from Public Investment Fund to invest into technology companies in the Middle East. Prior to his entrepreneurial career, Mr. Perks was a strategy consultant at McKinsey & Co., where he advised clients on growth strategies. Mr. Perks was also employed at Morgan Stanley where he primarily originated investment opportunities for private equity firms. Mr. Perks graduated from Oxford University with a first-class degree in English Literature. We believe Mr. Perks' qualifications to serve on our Board include his extensive experience investing in companies and serving as an executive and board member of companies.

Kathryn Cavanaugh has served as a member of our Board since January 2022 and previously served on the Capstar Special Purpose Acquisition Corp. board of directors from July 7, 2020 to January 2022. Since January 2019, Ms. Cavanaugh has served as the Managing Partner of Capstar Ventures LLC, an early stage venture capital firm that invests in the next generation of innovative consumer companies. From April 2016 to December 2018, Ms. Cavanaugh was a Partner at Grace Beauty Capital where she advised and invested in early stage companies in the consumer and retail sectors, including Rothy's, Inc., Parachute Home, Inc., Primary Kids, Inc., Supergoop!, LLC, MM.LaFleur, Inc., ThirdLove (MeCommerce, Inc.), Vengo, Inc., and Pixlee, Inc. From April 2015 to March 2016, Ms. Cavanaugh served as Director of Franchise Growth Strategy, Sales and Operations, and from March 2013 to February 2014 as a Board Director, for The Bar Method, Inc. From October 2011 to February 2014, Ms. Cavanaugh served as Vice President of Talent for Mainsail Partners, a growth equity firm. From September 2005 to June 2010, Ms. Cavanaugh worked at De Novo Ventures, an early stage healthcare venture capital firm, where she evaluated, executed and supported more than $350 million of equity investments in medical device, biotech and diagnostic companies. Ms. Cavanaugh received a Master of Business Administration from Harvard Business School in 2005 and Bachelor of Science degrees in Chemical Engineering and Biochemistry from the University of

Notre Dame in 1997. We believe Ms. Cavanaugh is well qualified to serve on our Board based on her extensive leadership and business experience, including her management positions and investment management background in the healthcare and consumer sectors.

Clayton Christopher has served as a member of our Board since January 2022 and previously served on the Capstar Special Purpose Acquisition Corp. board of directors from August 2021 to January 2022. Mr. Christopher is the co-founder and former Managing Partner of CAVU Venture Partners, an investment firm focused on best in class, better-for-you, food and beverage brands, which he left in 2020. Prior to CAVU, Mr. Christopher was the co-founder and CEO of Deep Eddy Vodka, which became one of the fastest growing spirits brands in the United States before being purchased by Heaven Hill Distilleries in August of 2015. He started his entrepreneurial journey at Sweet Leaf Tea, a company he started in 1998 with $12,000 in savings and a recipe from his grandmother. Sweet Leaf grew to a nationally recognized brand and was acquired by Nestle in 2011. Mr. Christopher is also the co-founder and Chairman of Waterloo Sparkling Water. He has also served on or currently serves on the board of directors of Nulo Pet Foods, Kite Hill, Rhythm Super Foods, REBBL, Kettle & Fire, Austin Eastciders, Good Culture, Bridge Equipment Leasing and SKU, a consumer products accelerator. In 2006, Mr. Christopher was awarded the Ernst & Young Entrepreneur of the year for Central Texas and is a recipient of Austin Under 40 Austinite of the Year Award. Mr. Christopher has also served on a number of non-profit boards over the years, including Mission Capital, Naturally Austin, Big Brothers Big Sisters and the University of Texas President's Innovation Board. We believe Mr. Christopher is well qualified to serve on our Board based on his vast entrepreneurial leadership, operational and investor experiences over the last 25 years.

Paul Fonteyne has served as a member of our Board since January 2022 and previously served as a member of the Gelesis, Inc. board of directors from May 2018 to January 2022. Mr. Fonteyne is currently the CEO of Thyron Pharmaceuticals Inc, a company he founded in April 2021. Mr. Fonteyne has more than 30 years of experience in the biopharmaceutical industry. Mr. Fonteyne is the retired Chairman and CEO of Boehringer-Ingelheim USA, or BI, where he served in leadership roles both in the US and globally for 15 years. He was President and CEO of BI from November of 2011, and subsequently its Chairman, until he retired January 2019. During this time, he led teams that grew BI's sales and earnings several fold in the USA and participated in acquisitions and divestitures that led to a significantly greater focus of BI's portfolio of companies in the US in two main segments of Animal Health and Human Pharmaceuticals. During his 30+ years in the pharmaceutical industry Mr. Fonteyne also held commercial leadership roles at Merck and Co. Inc. for 9 years, and Abbott Laboratories for 8 years. He has served on the board of PhRMA, chaired the National Pharmaceutical Council, served as Chair of an American Cancer Society initiative for New England (CEOs against Cancer). Prior to its reverse merger with Adicet Bio, he served on the board of ResTORbio Inc (and chair of the compensation committee) from January 2017 to September 2020. Previously, he was on the board of a specialty pharmaceutical company, AMAG, from November 2019 to October 2020 (prior to its sale to Apollo-backed Covis in November 2020). He also serves or recently served on the board of several public and private clinical stage biotechnology companies including DalCor (Chairman); Amylyx (AMLX), where he has served on the board of directors since April 2021; Apellis (APLS), where he has served on the board of directors since April 2020, Ypsomed AG (YPS), a device company, where he has served on the board of directors from July 2018 and an Animal Health Company, Covetrus (CVET), where he served on the board of directors from July 2021 to September 2022. Mr. Fonteyne received his M.B.A. from Carnegie-Mellon University and his MS in Chemical Engineering from the Polytechnic School at the University of Brussels. We believe Mr. Fonteyne's qualifications to serve on our Board include his extensive experience in the biopharmaceutical industry, as well as serving as a board member of companies in the biopharmaceutical industry.

Raju Kucherlapati has served as a member of our Board since January 2022 and previously served as a member of the Gelesis, Inc. board of directors from January 2016 to January 2022. Dr. Kucherlapati has also served as a member of the board of PureTech, Inc. since 2014. Dr. Kucherlapati has served as the Paul C. Cabot Professor of Genetics and Professor of Medicine at Harvard Medical School since September 2001. Dr. Kucherlapati was a founder and, from 1993 to 2005, a board member of Abgenix, a board member of Cell Genesys from 1988 to 1992 and a board member of Millennium Pharmaceuticals from 1993 to 2007. Dr. Kucherlapati was the first scientific director of the Harvard-Partners Center for Genetics and Genomics, a position he held from 2001 to 2008. Dr. Kucherlapati was elected as a fellow of the American Association for the Advancement of Science and has been a member of the National Academy of Medicine since 2008. Dr. Kucherlapati was named a member of the presidential commission for the study of bioethical issues during the Obama administration. Dr. Kucherlapati's laboratory at Harvard Medical School is involved in cloning many human disease genes with a focus on human syndromes with significant cardiovascular involvement, use of genetic/genomic approaches to understand the biology of cancer and the generation and characterization of genetically modified mouse models for cancer and other human disorders. His laboratory was a part of the Human Genome Project that was responsible for mapping and sequencing the human genome. Dr. Kucherlapati developed methods for modifying mammalian genes that lead to gene targeting in mice. He has developed many mouse models for human disease, including a large set of models for human colorectal cancer. His laboratory was a part of The Cancer Genome Atlas program that uses genetic/genomic approaches to understand the biology of cancer. He is a promoter of personalized/ precision medicine. Dr. Kucherlapati served on the editorial board of the New England Journal of Medicine and was editor-in-chief of the journal Genomics. Dr. Kucherlapati received his PhD from the University of Illinois. He trained at Yale and has held faculty positions at Princeton University, University of Illinois College of Medicine and the Albert Einstein College of Medicine prior to his appointment at Harvard. We believe Dr. Kucherlapati's qualifications to serve on our Board

include his experience in medicine and research and extensive experience founding and serving on boards of multi-billion-dollar companies.

Jane Wildman has served as a member of our Board since January 2022 and previously served as a member of the Gelesis, Inc. board of directors from April 2021 to January 2022. Since June 2021, Ms. Wildman has served as a senior advisor to Vestar, a private equity firm, and since 2018 has acted as an independent strategic consultant for various B2B and B2C companies across industries. Ms. Wildman has experience as a board member, president and global marketing leader. Her experience spans Fortune-25, mid-sized and start-up companies. As President from June 2014 to December 2017, and Board Member from January 2018 to December 2018, of Combe Incorporated, a personal-care consumer products company, Ms. Wildman successfully led the company to record sales and profit. Prior to Combe, from June 2009 to June 2014, Ms. Wildman was a Partner and Consultant with The Partnering Group, where clients included Fortune 50 companies like Walmart, Procter & Gamble and Nestle. Ms. Wildman spent over 25 years at Procter & Gamble, from June 1983 to December 2008, where she worked in beauty, health, baby, feminine care and food, with experience both in the United States and internationally. She served as global Vice President and led the global marketing organization for Pampers, P&G's largest brand. Ms. Wildman led the repositioning of the Pampers brand during her tenure there from September 2001 to December 2008. Ms. Wildman received a B.S. in Journalism from the University of Oregon and holds a Cornell Digital Marketing certification. We believe Ms. Wildman's qualifications to serve on our Board include her experience serving as a board member and experience as an executive across Fortune-25, mid-sized and start-up companies.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act and SEC regulations require our directors, certain officers and holders of more than 10% of our common stock to file reports of ownership on Form 3 and changes in ownership on Form 4 or 5 with the SEC. The reporting directors, officers and 10% stockholders are also required by SEC rules to furnish us with copies of all Section 16(a) reports they file. Based solely on our review of copies of such reports received and written representations from our directors and such covered officers, we believe that our directors and officers complied with all applicable Section 16(a) filing requirements during 2022, with the exception of one Form 4 filed late by Alessandro Sannino, dated June 13, 2022, reporting two transactions.

Audit Committee

Our Board has a separately designated audit committee. The members of our Board's audit committee currently include Alison Bauerlein, Raju Kucherlapati and Dominic Perks. Ms. Bauerlein currently serves as the chairperson of the audit committee. Under the NYSE listing rules and applicable SEC rules, we are required to have at least three members of the audit committee. The rules of the NYSE and Rule 10A-3 of the Exchange Act require that the audit committee of a listed company be composed solely of independent directors.

The Board determined that each of the members of the audit committee meet the independence requirements under NYSE and SEC rules and is financially literate, and Ms. Bauerlein qualifies as an "audit committee financial expert" as defined in SEC rules.

Recommendation of Director Nominees by Stockholders

There have been no material changes to the procedures by which our stockholders may recommend nominees to the board of directors.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The Code of Business Conduct and Ethics is available on the governance section of our website at https://ir.gelesis.com/governance/governance-documents. Information contained on or accessible through such website is not a part of this Amended Report, and the inclusion of the website address in this Amended Report is an inactive textual reference only. We intend to disclose any amendments to the Code of Business Conduct and Ethics, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements.

Item 11. Executive Compensation.

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies" as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for its principal executive officer and its two other most highly compensated executive officers. References in this section to "we", "our", "us", the "Company" and "Gelesis", generally refer to Gelesis Holdings, Inc.

Executive Compensation

This section discusses the material components of the executive compensation program offered to our principal executive officer and the two most highly compensated executive officers other than the principal executive officer, whom we refer to as our "named executive officers", or "NEOs". Our named executive officers in fiscal year 2022 were as follows:

(1) Yishai Zohar, our President, Chief Executive Officer, Class III Director and Co-Inventor;

(2) David Pass, our Chief Operating Officer and Chief Commercial Officer

(3) Elliot Maltz, our Chief Financial Officer, Treasurer, Chief Compliance Officer and Corporate Secretary

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations retarding future compensation programs. Actual compensation programs that we adopt could vary significantly from our historical practices and currently planned programs summarized in this discussion.

Executive Compensation Overview

Compensation Philosophy

Our executive compensation program has been designed to reinforce a strong link between pay and performance in order to: (i) attract leading talent; (ii) retain and motivate top performers; and (iii) promote and pay for performance culture with an emphasis on variable compensation. We continue to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require.

Compensation Elements

The compensation for Gelesis' named executive officers primarily consists of the following:

Compensation Element	Purpose
Base Salary	To provide stable and competitive income.
Annual Incentives	To motivate and reward short-term behaviors, actions and results that drive long-term value creation.
Equity Compensation	To encourage executives to maximize long-term shareholder value (provided in the form of options).

To accomplish both its short-term and long-term objectives, the compensation program emphasizes pay- for-performance, with two variable components. These variable components include annual and long-term incentives which are used to align each component of incentive compensation with Gelesis' short and long-term business objectives.

2022 Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by and paid to Gelesis' named executive officers for services rendered to Gelesis in all capacities during the fiscal years ended December 31, 2022 and December 31, 2021.

Name and Principal Position	Year	Salary ($)	Stock Awards[1] ($)	Option Awards[2] ($)	Non-Equity Incentive Plan Compensation[3] ($)	All Other Compensation[4] ($)	Total ($)
Yishai Zohar, President, Chief Executive Officer, Class III Director and Co-Inventor	2022	394,833	3,037,040	1,940,833	—	10,925	5,383,631
	2021	412,000	3,211,496	—	162,734	10,150	3,796,380
David Pass, Chief Operating Officer and Chief Commercial Officer	2022	355,350	1,667,611	931,599	—	10,925	2,965,486
Elliot Maltz, Chief Financial Officer Treasurer, Chief Compliance Officer and Corporate Secretary	2022	318,933	1,339,684	853,965	—	10,925	2,523,508
	2021	304,078	—	998,267	140,008	10,150	1,452,503

(1) Amounts shown reflect the grant date fair value of RSU awards granted during 2022 and 2021. The grant date fair value was computed in accordance with FASB ASC Topic 718 excluding any estimates of forfeitures related to service-based vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 16 to Gelesis' audited consolidated financial statements. These amounts do not correspond to the actual value that may be recognized by holders upon the vesting or settlement of the applicable awards, or subsequent sale of shares of common stock received pursuant to the settlement of such awards.

(2) Amounts shown reflect the grant date fair value of stock options granted during 2022 and 2021. The grant date fair value was computed in accordance with FASB ASC Topic 718 excluding any estimates of forfeitures related to service-based vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 16 to Gelesis' audited consolidated financial statements. These amounts do not correspond to the actual value that may be recognized by holders upon the vesting or exercise of the applicable option awards, or subsequent sale of shares of common stock received pursuant to the exercise of such option awards.

(3) Amounts shown represent discretionary performance-based bonuses earned for services performed during the fiscal years ended December 31, 2021. Although such performance-based bonuses are typically paid in cash, in an effort to preserve Gelesis' cash 100% of each NEO's performance-based bonus for the fiscal year ended December 31, 2021 was paid in the form of RSUs which will vest in full in February 2023 subject to such NEO's continued service relationship with us through such date. Each such RSU award will accelerate in full upon a "sale event" (as defined in our 2021 Stock Option and Incentive Plan, or the "2021 Plan"). No discretionary performance-based bonuses have been earned for the fiscal year ended December 31, 2022.

(4) Amounts shown represent employer matching contributions under our 401(k) plan.

Narrative Disclosure to the Summary Compensation Table

Base Salaries

The base salary component of compensation reflects the level of responsibility within Gelesis and is compared to similar positions in comparable companies in the biotechnology/pharmaceutical industry. The compensation committee sets the salary and bonus for each NEO, aside from the President & Chief Executive Officer's which is set by the Board based on recommendation from the Compensation Committee, and the compensation is subject to periodic review and adjustment. For the 2022 fiscal year, the base salary for Mr. Zohar was initially equal to $412,000, was decreased to $216,300 effective February 1, 2022, and was increased to $432,600 effective April 1, 2022. For the 2022 fiscal year, the base salary for Mr. Pass was initially equal to $370,800, was decreased to $194,670 effective February 1, 2022, and was increased to $389,340 effective April 1, 2022. For the 2022 fiscal year, the base salary for Mr. Maltz was initially equal to $318,270, was decreased to $250,638 effective February 1, 2022, and was increased to $334,184 effective April 1, 2022.

Annual Performance-Based Cash Bonuses

Each of our NEOs is eligible to earn a discretionary annual cash incentive bonus based on achievement of specified company and individual performance criteria established by the Gelesis board of directors in its discretion. For 2022, Mr. Zohar's target annual bonus was equal to 55% of his annual base salary, Mr. Pass' target annual bonus was equal to 44% of his annual base salary, and Mr. Maltz' target annual bonus was equal to 42% of his annual base salary.

Equity Compensation

Although we do not yet have a formal policy with respect to the grant of equity incentive awards to our NEOs, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period.

Employment Agreement with Yishai Zohar

We entered into an employment agreement with Yishai Zohar, dated July 16, 2021, which became effective January 13, 2022, pursuant to which we employ Mr. Zohar as our President and Chief Executive Officer on an "at will" basis. Mr. Zohar's employment agreement provides for his initial annual base salary to be $412,000 per year, subject to periodic increases at Gelesis' discretion. In addition, the employment agreement provides that Mr. Zohar is eligible to receive an annual performance bonus, initially targeted at fifty percent (50%) of his annual base salary.

Pursuant to the employment agreement, in the event of a termination of Mr. Zohar's employment by Gelesis without "cause" (as defined in the employment agreement) or by his resignation for "good reason"(as defined in the employment agreement), subject to Mr. Zohar's execution of a release of claims in favor of Gelesis and its affiliates, Mr. Zohar is entitled to receive (i) base salary continuation for twelve months following his termination date (subject to continued compliance with applicable restrictive covenant provisions), and (ii) subject to his copayment of premium amounts at the applicable active employees' rate and proper election to COBRA health continuation, monthly payments equal to the monthly employer contribution that Gelesis would have made to provide health insurance to Mr. Zohar if he had remained employed by Gelesis until the earliest of (A) the twelve month anniversary of his date of termination, (B) his eligibility for group health plan benefits under any other employer's group health plan, or (C) the cessation of his COBRA continuation rights. In addition, in the event of a termination of Mr. Zohar's employment by Gelesis without cause or by his resignation for good reason within twelve months after a "change in control" (as defined in the employment agreement), subject to Mr. Zohar's execution of a release of claims in favor of Gelesis and its affiliates, all unvested stock options and other stock-based awards held by Mr. Zohar will immediately accelerate and become fully exercisable or nonforfeitable as of his date of termination.

Employment Agreement with David Pass

We entered into an employment agreement with David Pass, dated July 27, 2021, which became effective January 13, 2022, pursuant to which we employ Mr. Pass as our Chief Operating Officer and Chief Commercial Officer on an "at will" basis. Mr. Pass' employment agreement provides for his initial annual base salary to be $370,800 per year, subject to periodic increases at Gelesis' discretion. In addition, the employment agreement provides that Mr. Pass is eligible to receive an annual performance bonus initially targeted at forty percent (40%) of his annual base salary.

Pursuant to the employment agreement, in the event of a termination of Mr. Pass' employment by Gelesis without "cause" (as defined in the employment agreement) or by his resignation for "good reason" (as defined in the employment agreement), subject to Mr. Pass'

execution of a release of claims in favor of Gelesis and its affiliates, Mr. Pass is entitled to receive (i) base salary continuation for twelve months following his termination date (subject to continued compliance with applicable restrictive covenant provisions), and (ii) subject to his copayment of premium amounts at the applicable active employees' rate and proper election to COBRA health continuation, monthly payments equal to the monthly employer contribution that Gelesis would have made to provide health insurance to Mr. Pass if he had remained employed by Gelesis until the earliest of (A) the six month anniversary of his date of termination, (B) his eligibility for group health plan benefits under any other employer's group health plan, or (C) the cessation of his COBRA continuation rights. In addition, in the event of a termination of Mr. Pass' employment by Gelesis without cause or by his resignation for good reason within twelve months after a "change in control" (as defined in the employment agreement), subject to Mr. Pass' execution of a release of claims in favor of Gelesis and its affiliates, all unvested stock options and other stock-based awards held by Mr. Pass will immediately accelerate and become fully exercisable or nonforfeitable as of his date of termination.

Employment Agreement with Elliot Maltz

We entered into an employment agreement with Elliot Maltz, dated July 19, 2021, which became effective January 13, 2022, pursuant to which we employ Mr. Maltz as our Chief Financial Officer, Treasurer, Chief Compliance Officer and Corporate Secretary on an "at will" basis. Mr. Maltz' employment agreement provides for his initial annual base salary to be $318,270 per year, subject to periodic increases at Gelesis' discretion. In addition, the employment agreement provides that Mr. Maltz is eligible to receive an annual performance bonus initially targeted at forty percent (40%) of his annual base salary.

Pursuant to the employment agreement, in the event of a termination of Mr. Maltz' employment by Gelesis without "cause" (as defined in the employment agreement) or by his resignation for "good reason" (as defined in the employment agreement), subject to Mr. Maltz' execution of a release of claims in favor of Gelesis and its affiliates, Mr. Maltz is entitled to receive (i) base salary continuation for twelve months following his termination date (subject to continued compliance with applicable restrictive covenant provisions), and (ii) subject to his copayment of premium amounts at the applicable active employees' rate and proper election to COBRA health continuation, monthly payments equal to the monthly employer contribution that Gelesis would have made to provide health insurance to Mr. Maltz if he had remained employed by Gelesis until the earliest of (A) the twelve month anniversary of his date of termination, (B) his eligibility for group health plan benefits under any other employer's group health plan, or (C) the cessation of his COBRA continuation rights. In addition, in the event of a termination of Mr. Maltz' employment by Gelesis without cause or by his resignation for good reason within twelve months after a "change in control" (as defined in the employment agreement), subject to Mr. Maltz' execution of a release of claims in favor of Gelesis and its affiliates, all unvested stock options and other stock-based awards held by Mr. Maltz will immediately accelerate and become fully exercisable or nonforfeitable as of his date of termination.

401(k) Plan

Gelesis maintains a retirement savings plan, or 401(k) plan, that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Under the Gelesis 401(k) Plan (the "401(k) Plan"), eligible employees may defer eligible compensation subject to applicable annual contribution limits imposed by the Code. Our employees' pre-tax contributions are allocated to each participant's individual account and participants are immediately and fully vested in their contributions. Under the provisions of the 401(k) Plan, Gelesis will make a safe harbor matching contribution equal to 100% of each participant's contributions up to 1% of the participant's compensation, and 50% of each participant's contributions that exceed 1% but are less than 6% of the participant's compensation. In addition, Gelesis may make discretionary profit sharing contributions, as determined by management. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

Employee Benefits

Our named executive officers are eligible to participate in the Gelesis employee benefit plans, including Gelesis medical, dental, vision, group life and accidental death and dismemberment insurance plans, in each case, on the same basis as all of our other employees.

Compensation Risk Assessment

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking. Our compensation programs are designed to encourage our executive officers and other employees to remain focused on both short-term and long-term strategic goals that drive shareholder value, in particular in connection with our pay-for-performance compensation philosophy. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on us.

Outstanding Equity Awards at 2022 Fiscal Year-End

The following table sets forth information concerning outstanding vested and unvested option awards and unvested equity awards held by each of Gelesis' named executive officers as of December 31, 2022.

	Option Awards(1)					Stock Awards		
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (X)		Market Value of Shares or Units of Stock that Have Not Vested(2)
Yishai Zohar, *President, Chief Executive Officer Class III Director, and Co-Inventor*	8/29/2014	441,070	—	3.11	8/29/2024			
	9/29/2014	4,525	—	4.05	2/16/2025			
	4/1/2016	390,595	—	4.05	9/7/2026			
	5/8/2017	77,760	—	4.05	6/15/2027			
	7/17/2018	453,605	—	4.05	7/17/2028			
	7/15/2020 (3)	777,663	259,221	4.26	7/15/2030			
	3/4/2022 (4)	—	898,867	3.33	3/4/2032			
						62,026	(5)	17,988
						898,867	(6)	260,671
David Pass, *Chief Operating Officer and Chief Commercial Officer*	9/1/2016	500,072	—	4.05	9/7/2026			
	7/17/2018	388,804	—	4.05	7/17/2028			
	7/15/2020	312,119	104,041	4.26	7/15/2030			
	3/4/2022	—	431,456	3.33	3/4/2032			
						51,763	(7)	15,011
						431,456	(6)	125,122
Elliot Maltz, *Chief Financial Officer, Treasurer, Chief Compliance Officer and Corporate Secretary*	3/25/2014	66,358	—	3.11	8/29/2024			
	3/25/2014	679	—	4.05	2/16/2025			
	3/26/2017	103,681	—	4.05	6/15/2027			
	7/17/2018	51,840	—	4.05	7/17/2028			
	7/15/2020 (3)	213,716	71,238	4.26	7/15/2030			
	5/14/2021 (3)	108,752	108,753	5.56	6/3/2031			
	3/4/2022 (4)	—	395,501	3.33	3/4/2032			
						36,474	(8)	10,577
						395,501	(6)	114,695

(1) Each of the outstanding option awards in the table above with an expiration date prior to September 2026 was granted pursuant to our 2006 Stock Incentive Plan (our "2006 Plan"). Each of the outstanding option awards in the table above with an expiration date in or after September 2026 but in or before June 2031 was granted pursuant to our 2016 Stock Option and Grant Plan (our "2016 Plan"). Each of the outstanding option awards in the table above with an expiration date after June 2031 was granted pursuant to our 2021 Stock Option and Incentive Plan (our "2021 Plan").

(2) Based on the fair market value of our common stock as of December 30, 2022, the last trading day of 2022, which was $0.29.

(3) The shares subject to this option vest over three years, with one-third of the option shares vesting on the one-year anniversary of the vesting commencement date, and two-thirds of the option shares vesting in equal quarterly installments thereafter, in each case subject to the NEO's continued service relationship with us.

(4) The shares subject to this option vest over four years, with one-fourth of the option shares vesting on the one-year anniversary of the vesting commencement date, and three-fourths of the option shares vesting in equal quarterly installments thereafter, in each case subject to the NEO's continued service relationship with us.

(5) Represents RSUs which vest with respect to 13,157 RSUs on February 10, 2023 and with respect to 48,869 RSUs on February 28, 2023.

(6) Represents RSUs which vest over four years, with 25% of such RSUs vesting on April 1, 2023 and the remaining 75% of such RSUs vesting in 12 equal quarterly installments thereafter.

(7) Represents RSUs which vest with respect to 11,841 RSUs on February 9, 2023 and with respect to 39,922 RSUs on February 23, 2023.

(8) Represents RSUs which vest with respect to 5,082 RSUs on February 6, 2023 and with respect to 31,392 RSUs on February 12, 2023.

Director Compensation

The following table presents the total compensation for each person who served as a non-employee member of our Board and received compensation for such service during the fiscal year ended December 31, 2022. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our Board in 2022. Mr. Zohar did not receive any additional compensation for their service as a member of our Board in 2022. Mr. Zohar's compensation for service as our President and Chief Executive Officer is presented above under the heading "Executive Compensation—2022 Summary Compensation Table".

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1]	Total ($)
Alison Bauerlein [2]	32,500	170,146	202,646
Dominic Perks [3]	26,431	164,069	190,500
Kathryn Cavanaugh [4]	25,229	162,551	187,780
Clayton Christopher [5]	26,431	164,069	190,500
Paul Fonteyne [6]	39,708	179,261	218,969
Raju Kucherlapati, Ph.D. [7]	30,035	168,628	198,663
Jane Wildman [8]	30,097	167,106	197,203

(1) Amounts shown reflect the grant date fair value of restricted stock units ("RSUs") granted during the fiscal year ended December 31, 2022, determined in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718 excluding any estimates of forfeitures related to service-based vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 16 to Gelesis' audited consolidated financial statements included elsewhere in this Form 10-K. These amounts do not correspond to the actual value that may be recognized by holders upon the vesting or settlement of the applicable awards, or subsequent sale of shares of common stock received pursuant to such awards.

(2) As of December 31, 2022, Ms. Bauerlein held 51,095 outstanding RSUs and options to purchase an aggregate of 103,680 shares of our common stock.

(3) As of December 31, 2022, Mr. Perks held 49,270 outstanding RSUs.

(4) As of December 31, 2022, Ms. Cavanaugh held 48,814 outstanding RSUs.

(5) As of December 31, 2022, Mr. Christopher held 49,270 outstanding RSUs.

(6) As of December 31, 2022, Mr. Fonteyne held 53,832 outstanding RSUs and options to purchase an aggregate of 220,318 shares of our common stock.

(7) As of December 31, 2022, Dr. Kucherlapati held 50,639 outstanding RSUs.

(8) As of December 31, 2022, Ms. Wildman held 50,182 outstanding RSUs and options to purchase an aggregate of 130,680 shares of our common stock.

Our compensation committee determines the annual compensation to be paid to the members of our Board, but has not yet adopted a formal non-employee director compensation policy.

For the 2022 fiscal year, our board of directors approved the following cash retainer compensation:

	Annual Retainer ($)
Board of Directors:	
All non-employee members	22,500
Additional retainer for non-executive Chair of the Board	15,000
Audit Committee:	
Chair	10,000
Non-Chair members	5,000
Compensation Committee:	
Chair	7,500
Non-Chair members	3,750
Nominating and Governance Committee:	
Chair	5,000
Non-Chair members	2,500

In addition, on March 4, 2022, our Board granted each non-employee director the following number of RSUs, each of which vest in full in March 2023, subject to each director's continued service relationship on such date:

Name	Number of RSUs
Alison Bauerlein	51,095
Dominic Perks	49,270
Kathryn Cavanaugh	49,270
Clayton Christopher	50,182
Paul Fonteyne	48,814
Raju Kucherlapati, Ph.D.	53,832
Jane Wildman	50,639

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information regarding the beneficial ownership of our voting shares by:

- each person who is known to be the beneficial owner of more than 5% of our voting shares;
- each of our named executive officers and directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security. Under those rules, beneficial ownership includes securities that the individual or entity has the right to acquire, such as through the exercise of stock options, within 60 days. Shares subject to options that are currently exercisable or exercisable within 60 days of March 17, 2023 are considered outstanding and beneficially owned by the person holding such options for the purpose of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, we believe that the persons and entities named in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them. Unless otherwise noted, the business address of each of the directors and executive officers of Gelesis Holdings is 501 Boylston Street, Suite 6102, Boston, MA 02116. The percentage of beneficial ownership is calculated based on 73,332,588 shares of Common Stock outstanding as of March 24, 2023.

Name and Address of Beneficial Owner	Number of Shares	%
Directors and Officers:		
Yishai Zohar[1]	3,683,415	5.0 %
David Pass[2]	1,537,846	2.1 %
Elliot Maltz[3]	862,993	1.2
Alessandro Sannino[4]	2,179,085	3.0 %
Raju Kucherlapati[5]	190,264	*
Dominic Perks[6]	49,270	*
Alison Bauerlein[7]	114,456	*
Jane Wildman[8]	136,582	*
Kathryn Cavanaugh[9]	61,639	*
Paul Fonteyne[10]	263,350	*
Clayton Christopher[11]	1,262,768	1.7 %
All Directors and Executive Officers as a group (11 individuals)	10,341,668	14.1 %
Five Percent Holders:		
PureTech Health LLC[12]	17,099,310	23.3 %
SSD2 LLC and affiliated entities[13]	13,405,732	18.3 %
HPSO SPV Limited[14]	12,181,993	16.6 %
Pacific Investment Management Company LLC[15]	3,760,000	5.1 %
CMS Medical Venture Investment (HK) Limited[16]	4,901,770	6.7 %
R. Steven Hicks[17]	4,232,391	5.8 %

* Less than one percent.

(1) Consists of 465,121 shares of Common Stock, options to purchase up to 2,572,747 shares of Common Stock and 675,547 RSUs which have vested or which will vest within 60 days of March 17, 2023.

(2) Consists of options to purchase up to 1,378,219 shares of Common Stock and 159,627 RSUs which have vested or which will vest within 60 days of March 17, 2023.

(3) Consists of options to purchase up to 727,644 shares of Common Stock and 135,349 RSUs which have vested or which will vest within 60 days of March 17, 2023.

(4) Consists of 138,177 shares of Common Stock issued to Mr. Sannino, 623,727 shares of Common Stock issued to One S.r.l. ("One"), an entity in which our subsidiary, Gelesis, Inc., holds a 10% equity interest, options to purchase up to 425,733 shares of Common Stock and 17,242 RSUs which have vested or which will vest within 60 days of March 17, 2023, issued to Mr. Sannino, and warrants to purchase up to 974,206 shares of Common Stock issued to Mr. Sannino. Mr. Sannino is a co-founder of One and may be deemed to have shared beneficial ownership of the shares held directly by One. Mr. Sannino disclaims beneficial ownership over the shares beneficially owned by One, except to the extent of any pecuniary interest.

(5) Consists of 139,625 shares of Common Stock and 50,639 RSUs which have vested or which will vest within 60 days of March 17, 2023.

(6) Consists of 49,270 RSUs which have vested or which will vest within 60 days of March 17, 2023.

(7) Consists of options to purchase up to 63,361 shares of Common Stock and 51,095 RSUs which have vested or which will vest within 60 days of March 17, 2023.

(8) Consists of options to purchase up to 86,400 shares of Common Stock and 50,182 RSUs which have vested or which will vest within 60 days of March 17, 2023.

(9) Consists of 12,825 shares of Common Stock and 48,814 RSUs which have vested or which will vest within 60 days of March 17, 2023.

(10) Consists of options to purchase 209,518 shares of Common Stock and 53,832 RSUs which have vested or which will vest within 60 days of March 17, 2023.

(11) Consists of 461,498 shares of Common Stock, 49,270 RSUs which have vested or which will vest within 60 days of March 17, 2023, and warrants to purchase up to 752,000 shares of Common Stock.

(12) Consists of 16,727,582 shares of Common Stock, options to purchase up to 155,520 shares of Common Stock which have vested or which will vest within 60 days of March 17, 2023, and warrants to purchase up to 216,208 shares of Common Stock. Voting and investment power over the shares held by PureTech Health LLC is exercised by its parent entity, PureTech Health plc. The board of directors of PureTech Health plc consists of Dr. Bharatt Chowrira, Dr. Raju Kucherlapati, Dr. John LaMattina, Dr. Robert Langer, Ms. Kiran Mazumdar-Shaw, Ms. Sharon Barber-Lui, Mr. Christopher Viehbacher, Dr. Joseph Bolen, Dr. Robert Horvitz, Dr. Dennis Ausiello and Ms. Daphne Zohar. None of the members of the board of directors of PureTech Health plc or PureTech Health LLC has individual voting or investment power with respect to such shares. The address for PureTech Health LLC and the individuals listed above is c/o PureTech Health LLC, 6 Tide Street, Boston, Massachusetts 02210.

(13) Consists of 12,056,626 shares of Common Stock, options to purchase up to 51,840 shares of Common Stock which have vested or which will vest within 60 days of March 17, 2023, and warrants to purchase up to 1,297,266 shares of Common Stock. Elon S. Boms and Andrew D. Wingate are co-managers of Bomsmaster LLC, which is the sole member of SSD2 LLC. Bomsmaster LLC is controlled by KLP Enterprises LLC. Mr. Wingate is the sole manager of KLP Enterprises LLC. Bomsmaster LLC, KLP Enterprises LLC, Mr. Boms and Mr. Wingate may each be deemed to share voting and dispositive power over the shares. Each of them disclaims beneficial ownership over the shares, except to the extent of any pecuniary interest therein. The address for each of these persons is 195 Church Street, 15th Floor, New Haven, Connecticut 06510. SSD2 LLC and the KLP Enterprises LLC may be deemed to be members of a "group," within the meaning of Section 13(d)(3) of the Exchange Act, comprised of the SSD2 LLC and the KLP Enterprises LLC.

(14) Consists of 12,181,993 shares of Common Stock held by HPSO SPV Limited ("HPSO SPV"). HPSO SPV, organized as a Guernsey limited company, is a wholly owned subsidiary of HP Special Opportunities Fund I LP, which is managed by Hambro Perks Asset Management Limited, a Guernsey limited company (the "Manager"). The Manager exercises exclusive voting and dispositive power over the shares held by HPSO SPV. The Manager disclaims beneficial ownership of these shares except to the extent of its pecuniary interest in HPSO SPV. The business address of HPSO SPV and of the Manager is Sarnia House, Le Truchot, St. Peter Port, Guernsey GY1 4NA. Dominic Perks, a member of our Board, is the founder and Chief Executive Officer of Hambro Perks Limited, which is the limited partner of HP Special Opportunities Fund I LP, which in turn, owns 100% of the shares of HPSO SPV. Mr. Perks disclaims beneficial ownership interest of the securities held by HP Special Opportunities Fund I LP and HPSO SPV except to the extent of his pecuniary interest therein, if any.

(15) Consists of warrants to purchase up to 1,880,000 shares of Common Stock held by GCCU VI LLC ("GCCU") and warrants to purchase up to 1,880,000 shares of Common Stock issuable upon exercise of the Private Placement Warrants held by TOCU XXIX LLC ("TOCU"). GCCU and TOCU are private funds of which Pacific Investment Management Company LLC ("PIMCO") is the investment adviser. PIMCO Global Credit Opportunity Master Fund LDC ("PIMCO Global") is the member manager of GCCU and PIMCO Tactical Opportunity Master Fund LDC ("PIMCO Tactical") is the member manager of TOCU. GCCU and TOCU hold the securities reported herein for the benefit of their respective investors, in their respective investment advisory accounts managed by PIMCO, and each such fund has the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, the securities that it holds. Michelle Wilson-Clarke and Julie O'Hara, who are directors of PIMCO Global and PIMCO Tactical, share voting and investment discretion with respect to the securities held of record by GCCU and TOCU and may be deemed to have shared beneficial ownership of the securities held directly by TOCU and GCCU. The address of GCCU and TOCU is Windward 3, Regatta Office Park, West Bay Road, PO Box 30872, Grand Cayman KY1-1204, Cayman Islands.

(16) Consists of 4,501,770 shares of Common Stock and warrants to purchase up to 400,000 shares of Common Stock held by CMS Medical Venture Investment (HK) Limited ("CMS HK"). CMS HK is a wholly owned subsidiary of China Medical System Holdings Limited ("CMS"). Each of CMS HK and CMS is deemed to be the beneficial owner with shared dispositive and voting power with respect to the shares of Common Stock held by CMS HK. The principal business address of CMS HK and CMS is Unit 2106, 21/F, Island Place Tower, 510 King's Road, North Point, Hong Kong, China.

(17) Consists of 1,224,391 shares of Common Stock and warrants to purchase up to 3,008,000 shares of Common Stock.

Equity Compensation Plan Information (Information as of December 31, 2022)

The following table provides information as of December 31, 2022 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Weighted Average Exercise Price of Outstanding Options, Warrants and Rights		Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)	
Equity compensation plans approved by stockholders [1]	16,881,549	[2]	$ 3.97	[3]	6,910,252	[4]

(1) Includes our 2006 Plan, 2016 Plan and 2021 Plan.

(2) Includes (i) 12,798,479 shares of our common stock issuable upon exercise of outstanding stock options, and (ii) 4,083,070 shares of our common stock issuable upon vesting of RSUs.

(3) Represents the weighted-average exercise price of options outstanding under our 2006 Plan, 2016 Plan and 2021 Plan.

(4) As of December 31, 2022, a total of 6,910,252 shares of our common stock have been reserved for issuance pursuant to the 2021 Plan, which number excludes the 2,933,000 shares that were added to the plan as a result of the automatic annual increase on each January 1, 2023. The 2021 Plan provides that the number of shares reserved and available for issuance under the plan automatically increases each January 1, beginning on January 1, 2023, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. The shares of common stock underlying any awards that are forfeited cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated, other than by exercise, under the 2021 Plan will be added back to the shares of common stock available for issuance under the 2021 Plan.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The following is a description of transactions or series of transactions since January 1, 2021 to which we were or will be a party, in which:

- the amount involved in the transaction exceeds, or will exceed, $120,000 (or, if less, 1% of the average of our total assets amounts at December 31, 2021 and 2022); and
- in which any of our executive officers, directors or holder of five percent or more of any class of our capital stock, including their immediate family members or affiliated entities, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this Form 10-K under “Director Compensation” and “Executive Compensation.”

Certain Relationships and Related Person Transactions

PureTech

On December 13, 2021, we executed convertible promissory note agreements in the aggregate amount of $27.0 million, including a note agreement in the aggregate amount of $15.0 million payable to PureTech. These convertible promissory notes bore interest at 10.0% and were settled in cash for principal plus accrued interest on January 19, 2022.

On July 25, 2022, we executed convertible promissory note agreements in the aggregate amount of $25 million, including a note agreement to PureTech in the amount of $15.0 million. These convertible promissory notes bear interest at a rate of 15% per annum and may be repaid with proceeding from future financing subject to certain conditions set forth in the promissory notes, or payable at December 31, 2023 with an option to convert to equity.

On February 21, 2023, the Company entered into a Note and Warrant Purchase Agreement with PureTech Health LLC, pursuant to which the Company issued a short term convertible senior secured note in the aggregate principal amount of $5.0 million and warrants to purchase 23,688,047 shares of Common Stock. The warrants have an exercise price of $0.2744 and may not be exercised prior to the receipt of Stockholder approval. The short term convertible senior secured note bears interest at a rate of 12% per annum, and matures on July 31, 2023, unless earlier converted or the maturity is extended as described within the definitive Agreements. The Company may issue an additional $5.0 million to PureTech upon mutual acceptance of the Company meeting certain conditions.

One S.r.l

In 2008, in connection with our entry into a patent license and assignment agreement with One, we and one of the founders of One, who is also a stockholder of the Company, executed a consulting agreement for the development of the underlying intellectual property. We incurred costs for consulting services received from such founder totaling $0.3 million during each of the years ended December 31, 2022 and 2021, respectively. We had outstanding accrued expenses to the founder of less than $0.1 million at December 31, 2022 and December 31, 2021, respectively.

In connection with an amended and restated master agreement with One, the Company acquired a 10.0% equity interest in One. €2.5 million and €0 was paid to the One shareholders by us towards this acquisition during the years ended December 31, 2022 and 2021, respectively. We had remaining undiscounted payments of €2.5 million due to One as of December 31, 2022.

Additionally, we incurred royalty expense of $0.5 million and $0.2 million in connection with the One royalty agreement during the years ended December 31, 2022 and 2021, respectively.

CMS Strategic Partnership

In June 2020, we entered into a strategic partnership with CMS for the commercialization of Plenity in Greater China (including Mainland China, Hong Kong, Macau, and Taiwan), Singapore and United Arab Emirates. In connection with this agreement, we sold 1,158,077 shares of Series 3 Growth to CMS for an aggregate purchase price of $20.0 million. In addition, we granted CMS a license to use our intellectual property and the rights to sell Plenity in the aforementioned territory in exchange for a one-time, non- refundable and non-creditable upfront fee of $15.0 million, a time-based milestone payment of $5.0 million, with the potential for an additional $388.0 million in future regulatory and sales milestone payments with the potential for an additional $388.0 million in future regulatory and sales milestone payments based on the aggregate net sales of all products in the aforementioned territory during a calendar year.

On August 4, 2022, we amended the CMS Agreement, under which the one-time regulatory approval milestone payment of $5.0 million provided for in the original agreement became immediately payable. Additionally, the amendment expands the CMS Territory include Brunei, Myanmar, Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Thailand and Vietnam and provides that the minimum annual royalty term for CMS Territory will commence January 2024 (rather than January 2022 as previously provided under the original CMS Agreement). The Company also issued to CMS a warrant to purchase up to 400,000 shares of common stock, par value $0.0001 per share, at an exercise price of $0.01 per share. The discounted one-time regulatory approval milestone, which had a carrying value of $4.2 million and $4.1 million as of August 4, 2022 and December 31, 2021, respectively, was fully collected upon execution of the CMS amendment.

Policies and Procedures for Related Party Transactions

We have adopted a written related person transaction approval and disclosure policy that sets forth the following policies and procedures for the review and approval or ratification of related person transactions.

A "Related Person Transaction" is a transaction, arrangement or relationship in which we or any of our subsidiaries was, is or will be a participant, the amount of which involved exceeds $120,000, and in which any related person had, has or will have a direct or indirect material interest. A "Related Person" means:

- any person who is, or at any time during the applicable period was, one of our officers or one of our directors;
- any person who is known by us to be the beneficial owner of more than five percent (5%) of its voting stock;
- any immediate family member of any of the foregoing persons, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, daughter-in-law, brother-in-law or sister-in-law of a director, officer or a beneficial owner of more than five percent (5%) of its voting stock, and any person (other than a tenant or employee) sharing the household of such director, officer or beneficial owner of more than five percent (5%) of its voting stock; and
- any firm, corporation or other entity in which any of the foregoing persons is a partner or principal or in a similar position or in which such person has a ten percent (10%) or greater beneficial ownership interest.

We have policies and procedures designed to minimize potential conflicts of interest arising from any dealings we may have with our affiliates and to provide appropriate procedures for the disclosure of any real or potential conflicts of interest that may exist from time to time. Specifically, each potential related party transaction will be reviewed by, and require the approval of, a majority of the disinterested members of our Board.

Indemnification Of Directors And Officers

We have entered into indemnification agreements with each of our directors and executive officers. The indemnification agreements and our Certificate of Incorporation and Bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Director Independence

Our Board of Directors has determined that all of our directors other than Mr. Zohar are independent under applicable SEC rules and NYSE listing standards. Applying these same rules, our Board has determined that all members of the audit committee, the compensation committee, and the nominating and corporate governance committee are independent.

Item 14. Principal Accountant Fees and Services.

Our independent registered public accounting firm is KPMG LLP ("KPMG"), Boston, MA, PCAOB ID Number 185. KPMG was appointed our independent registered accounting firm in May 2022 and served as the independent registered public accounting firm of Legacy Gelesis since 2015. Marcum LLP ("Marcum"), was CPSR's independent registered public accounting firm prior to the Business Combination. As previously disclosed in a Current Report on Form 8-K, filed May 10, 2022, Marcum was informed that it would be replaced by KPMG as Gelesis' independent registered public accounting firm.

The following is a summary of KPMG fees incurred by us (including Legacy Gelesis) for services rendered in conjunction with the years ended December 31, 2022 and 2021:

		December 31,	
Type of Fee	**Description**	**2022**	**2021**
Audit Fees	For the audits of the Company's annual financial statements, reviews of the Company's quarterly financial statements, as well as fees incurred in connection with the preparation and filing of registration statements with the SEC.	$ 747,000	$ 527,500
Audit-Related Fees	Fees billed for services reasonably related to the performance of the audit or review of the Company's financial statements, including fees related to our 8-K filings, S-1 and S-8 filings, comfort letter procedures which are not reported under the caption "Audit Fees" above, and VAT declaration and related compliance procedures for our Italian subsidiary, Gelesis S.r.l.	211,000	652,000
Total		$ 958,000	$ 1,179,500

Pre-Approval of Services. The audit committee has a policy requiring it to pre-approve all audit and non-audit services performed by the Company's independent auditors. The audit committee may delegate pre-approval authority to one or more members of the audit committee, including the Chair of the audit committee, who shall present all decisions to pre-approve an activity to the full audit committee at its first meeting following such decision. When pre-approving all services by the independent auditor, the audit committee may consider whether the provision of the services is compatible with maintaining the independent auditor's independence.

During our 2022 fiscal year, all audit, audit-related and other fees for services performed by KPMG were pre-approved by the audit committee in compliance with applicable SEC requirements.

Item 15. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Gelesis Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the Company on January 20, 2022)
3.2	Amended and Restated Bylaws of Gelesis Holdings, Inc. (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed by the Company on January 20, 2022)
4.1	Amended and Restated Registration and Stockholder Rights Agreement, dated January 13, 2021, by and among the Company and the stockholders party thereto (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Company on January 20, 2022).
4.2	Description of Securities of Gelesis Holdings, Inc. (incorporated by reference to Exhibit 4.3 to the Annual Report on Form 10-K for the year ended December 31, 2021 filed by the Company on April 1, 2021).
10.1	Form of Amended and Restated Registration and Stockholder Rights Agreement (incorporated by reference to Exhibit D to Annex A to the Proxy Statement/Prospectus filed by the Company on December 27, 2021).
10.2+	Gelesis Holdings, Inc. 2021 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by the Company on January 20, 2022).
10.3+	Gelesis Holdings, Inc. 2016 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-4 filed by the Company on August 10, 2021).
10.4*+	Gelesis Holdings, Inc. 2006 Stock Incentive Plan.
10.5	Royalty Assignment Agreement, dated as of December 18, 2009, by and among PureTech Ventures, LLC, Gelesis, Inc. and Gelesis LP (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-4/A filed by the Company on October 5, 2021).
10.6†	Pharmaceutical Distribution Agreement, dated as of Feb 12, 2020, between Gelesis, Inc. and Specialty Medical Drugstore, LLC (d/b/a GoGoMeds) (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-4/A filed by the Company on October 5, 2021).
10.7†	License, Collaboration and Supply Agreement, dated June 18, 2020, by and between Gelesis, Inc. and CMS Bridging DMCC (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-4/A filed by the Company on October 5, 2021).
10.8+	Employment Agreement, dated as of July 16, 2021, by and between Gelesis Holdings, Inc. and Yishai Zohar (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed by the Company on January 20, 2022).
10.9+	Employment Agreement, dated as of July 27, 2021, by and between Gelesis Holdings, Inc. and David Pass (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed by the Company on January 20, 2022).
10.10+	Employment Agreement, dated as of July 19, 2021, by and between Gelesis Holdings, Inc. and Elliot Maltz (incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K filed by the Company on January 20, 2022).
10.11	Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.12 to the Current Report on Form 8-K filed by the Company on January 20, 2022).
10.12	Form of Officer Indemnification Agreement (incorporated by reference to Exhibit 10.13 to the Current Report on Form 8-K filed by the Company on January 20, 2022).
10.13†	Third Amended and Restated Supply and Distribution Agreement, dated June 14, 2022, between Gelesis Holdings, Inc. and Roman Health Pharmacy LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company on June 21, 2022).
10.14	Form of Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company on July 29, 2022).
10.15	Form of Warrant to Purchase Common Stock of Gelesis Holdings, Inc (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Company on July 29, 2022).
10.16	Warrant to Purchase Common Stock of Gelesis Holdings, Inc., dated August 4, 2022, issued to CMS Bridging DMCC (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by the Company on August 10, 2022).
10.17	Amended and Restated Warrant to Purchase Common Stock of Gelesis Holdings, Inc., dated August 9, 2022 (incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K filed by the Company on August 10, 2022).
10.18	Amendment, dated August 4, 2022, to License, Collaboration and Supply Agreement by and between the Subsidiary and CMS Bridging DMCC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company on August 10, 2022).
10.19	Common Stock Purchase Agreement, dated August 11, 2022, by and between the Company and B. Riley Principal Capital II, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Company on August 12, 2022).

10.20	Registration Rights Agreement, dated August 11, 2022, by and between the Company and B. Riley Principal Capital II, LLC (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Company on August 12, 2022).
10.21†	Separation and General Release Agreement, effective September 30, 2022, by and between the Company and Mr. David Abraham (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q filed by the Company on November 14, 2022).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Annual Report on Form 10-K for the year ended December 31, 2021 filed by the Company on April 1, 2021).
24.1	Power of Attorney (included on signature page of this Form 10-K).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

† Certain portions of this exhibit are omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.

* Filed herewith.

** These certifications will not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act except to the extent specifically incorporated by reference into such filing.

+ Denotes management compensatory plan, contract or arrangement.

Item 16. Form 10-K Summary

Not applicable.

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 thereunto duly authorized.

GELESIS HOLDINGS, INC.

Date: March 28, 2023

By: /s/ Yishai Zohar
Yishai Zohar
Chief Executive Officer
(Principal Executive Officer)

Date: March 28, 2023

By: /s/ Elliot Maltz
Elliot Maltz
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Yishai Zohar, Elliot Maltz and David Abraham, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys-in-fact and agents, or his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ Yishai Zohar Yishai Zohar	Chief Executive Officer and Director *(Principal Executive Officer)*	March 28, 2023
/s/ Elliot Maltz Elliot Maltz	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 28, 2023
/s/ Paul Fonteyne Paul Fonteyne	Director	March 28, 2023
/s/ Raju Kucherlapati Raju Kucherlapati	Director	March 28, 2023
/s/ Jane Wildman Jane Wildman	Director	March 28, 2023
/s/ Dominic Perks Dominic Perks	Director	March 28, 2023
/s/ Ali Bauerlein Ali Bauerlein	Director	March 28, 2023
/s/ Clayton Christopher Clayton Christopher	Director	March 28, 2023

/s/ Kathryn Cavanaugh

Kathryn Cavanaugh	Director	March 28, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Gelesis Holdings, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Gelesis Holdings, Inc. and subsidiaries (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, non-controlling interest, redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses and cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2015.

Boston, Massachusetts
March 28, 2023

GELESIS HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,412	$ 28,397
Accounts receivable	1,233	731
Grants receivable	3,359	9,172
Inventories	6,865	13,503
Prepaid expenses and other current assets	4,627	14,203
Total current assets	23,496	66,006
Property and equipment, net	59,335	58,515
Operating lease right-of-use assets	1,520	2,016
Intangible assets, net	13,413	15,680
Other assets	5,560	4,084
Total assets	$ 103,324	$ 146,301
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable, including due to related party of $135 and $147, respectively	$ 4,131	$ 10,066
Accrued expenses and other current liabilities, including due to related party of $2,809 and $5,664, respectively	10,468	13,660
Deferred income	27,793	32,370
Operating lease liabilities	597	541
Convertible promissory notes held at fair value, including due to related party of $22,082 and $27,128, respectively	27,403	27,128
Notes payable, including due to related party of $2,007 and $0, respectively	7,954	1,950
Warrant liabilities	—	15,821
Total current liabilities	78,346	101,536
Deferred income	9,544	8,914
Operating lease liabilities	967	1,519
Notes payable, including due to related party of $13,659 and $16,523, respectively	25,342	35,131
Warrant liabilities	130	—
Earnout liability	563	—
Other long-term liabilities, including due to related party of $674 and $2,416, respectively	898	5,588
Total liabilities	115,790	152,688
Commitments and contingencies (Note 19)		
Noncontrolling interest	12,590	11,855
Legacy Gelesis redeemable convertible preferred stock, $0.0001 par value – zero shares issued and outstanding at December 31, 2022; 51,730,762 shares authorized at December 31, 2021; and 48,566,655 shares issued and outstanding at December 31, 2021	—	311,594
Stockholders' deficit:		
Preferred stock, $0.0001 par value - 250,000,000 shares authorized at December 31, 2022; zero shares issued and outstanding at December 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value – 900,000,000 shares authorized at December 31, 2022; 73,325,022 shares issued and outstanding at December 31, 2022; 125,961,571 shares authorized at December 31, 2021; 6,248,192 shares issued and outstanding at December 31, 2021	7	1
Additional paid-in capital	297,468	(64,549)
Accumulated other comprehensive income	104	219
Accumulated deficit	(322,635)	(265,507)
Total stockholders' deficit	(25,056)	(329,836)
Total liabilities, noncontrolling interest, redeemable convertible preferred stock and stockholders' deficit	$ 103,324	$ 146,301

The accompanying notes are an integral part of these consolidated financial statements.

GELESIS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	For the Year Ended December 31,	
	2022	**2021**
Revenue:		
Product revenue, net	$ 25,558	$ 11,185
Licensing revenue	209	—
Total revenue, net	25,767	11,185
Operating expenses:		
Costs of goods sold, including related party expenses of $1,027 and $447, respectively	27,558	9,983
Selling, general and administrative, including related party expenses of $504 and $494, respectively	99,135	71,041
Research and development, including related party expenses of $231 and $255, respectively	18,613	12,867
Amortization of intangible assets	2,267	2,267
Total operating expenses	147,573	96,158
Loss from operations	(121,806)	(84,973)
Change in the fair value of earnout liability	58,308	—
Change in the fair value of convertible promissory notes	(2,559)	(128)
Change in the fair value of warrants	7,084	(7,646)
Interest expense, net	(991)	(1,364)
Other income, net	4,664	781
Loss before income taxes	(55,300)	(93,330)
Provision for income taxes	480	17
Net loss	(55,780)	(93,347)
Accretion of Legacy Gelesis senior preferred stock to redemption value	(37,934)	(94,134)
Accretion of noncontrolling interest put option to redemption value	(253)	(376)
Income allocated to noncontrolling interest holder	(1,095)	—
Net loss attributable to common stockholders	$ (95,062)	$ (187,857)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.35)	$ (32.89)
Weighted average common shares outstanding—basic and diluted	70,300,772	5,712,042

The accompanying notes are an integral part of these consolidated financial statements.

GELESIS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	For the Year Ended December 31,	
	2022	**2021**
Net loss	$ (55,780)	$ (93,347)
Other comprehensive loss:		
Foreign currency translation adjustment	(115)	(719)
Total other comprehensive loss	(115)	(719)
Comprehensive loss	$ (55,895)	$ (94,066)

The accompanying notes are an integral part of these consolidated financial statements.

GELESIS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF NONCONTROLLING INTEREST, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share and per share data)

	Noncontrolling interest	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Deficit
		Shares	Amount	Shares	Amount				
Balance at January 1, 2021	$ 12,429	18,446,525	$ 213,524	2,155,490	$ 1	$ 23,907	$ 938	$ (171,784)	(146,938)
Accretion of senior preferred stock to redemption value			94,134			(94,134)			(94,134)
Stock based compensation expense						5,532			5,532
Exercise of stock options				255,062		146			146
Exercise of warrants		290,411	3,934						—
Accretion of put option	376							(376)	(376)
Net loss								(93,347)	(93,347)
Foreign currency translation adjustment	(950)						(719)		(719)
Balance at December 31, 2021	$ 11,855	18,736,936	$ 311,592	2,410,552	$ 1	$ (64,549)	$ 219	$ (265,507)	$ (329,836)
Merger recapitalization		29,829,719	$ -	3,837,640	—	—	—	—	
Balance at December 31, 2021	$ 11,855	48,566,655	$ 311,592	6,248,192	$ 1	$ (64,549)	$ 219	$ (265,507)	$ (329,836)
Accretion of senior preferred stock to redemption value		-	$ 37,934			(37,934)			(37,934.00)
Conversion of redeemable convertible preferred stock into common stock upon merger recapitalization		(48,566,655)	$ (349,526)	48,566,655	—	349,526			349,526.00
Proceeds from Business Combination, net of issuance costs and assumed liabilities				17,399,440	6	69,359			69,365.00
Conversion of preferred stock warrants into common stock warrants upon merger recapitalization						16,747			16,747.00
Issuance of contingent earnout liability upon merger recapitalization						(58,871)			(58,871.00)
Issuance of private placement warrants upon merger recapitalization						(8,140)			(8,140.00)
Stock based compensation expense						29,777			29,777.00
Exercise of stock options				207,033	—	120			120.00
Exercise of warrants				176,126	—	4			4.00
Release of restricted stock units				337,969	—	—			-
Sale of common stock, net of issuance costs				355,361	—	500			500.00
Issuance of commitment shares				34,246	—	39			39.00
Issuance of common stock warrants				—	—	890			890.00
Accretion of put option	253							(253)	(253.00)
Income allocated to noncontrolling interest holder	1,095							(1,095)	(1,095.00)
Net loss								(55,780)	(55,780.00)
Foreign currency translation adjustment	(613)						(115)		(115.00)
Balance at December 31, 2022	$ 12,590	—	$ -	73,325,022	$ 7	$ 297,468	$ 104	$ (322,635)	$ (25,056)

The accompanying notes are an integral part of these consolidated financial statements.

GELESIS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the Year Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (55,780)	$ (93,347)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of intangible assets	2,267	2,267
Increase in inventory reserves	13,334	—
Reduction in carrying amount of right-of-use assets	475	449
Depreciation	3,221	1,524
Stock-based compensation	29,777	5,532
Issuance of common stock commitment shares	500	—
Gain on sales of common stock	(1)	—
Unrealized loss on foreign currency transactions	608	(37)
Non-cash interest expense	215	173
Gain on CMS amendment	(209)	—
Loss on One S.r.l. amendment	278	—
Accretion on marketable securities	—	(1)
Change in the fair value of earnout liability	(58,308)	—
Change in the fair value of warrants	(7,084)	7,646
Change in the fair value of convertible promissory notes	2,559	128
Change in fair value of One S.r.l. call option	(1,462)	1,024
Change in fair value of interest rate swap contract	(856)	146
Changes in operating assets and liabilities:		
Accounts receivable	(502)	70
Grants receivable	5,216	(1,723)
Prepaid expenses and other current assets	6,147	(8,029)
Inventories	(6,249)	(8,645)
Other assets	(449)	107
Accounts payable	(5,415)	2,604
Accrued expenses and other current liabilities	(269)	8,709
Operating lease liabilities	(474)	(440)
Deferred income	(3,395)	33,140
Other long-term liabilities	(1,872)	(6,588)
Net cash used in operating activities	(77,728)	(55,291)
Cash flows from investing activities:		
Purchases of property and equipment	(9,120)	(19,917)
Maturities of marketable securities	—	24,000
Net cash (used in) provided by investing activities	(9,120)	4,083
Cash flows from financing activities:		
Proceeds from Business Combination, net of transaction costs	70,479	—
Principal repayment of notes payable	(2,033)	(302)
Repayment of convertible promissory notes	(27,284)	—
Proceeds from convertible promissory notes	25,000	27,000
Proceeds from issuance of promissory notes (net of issuance costs of $0 and $207, respectively)	—	5,679
Proceeds from exercise of warrants	4	10
Proceeds from exercise of share-based awards	120	146
Proceeds from sales of common stock, net of issuance costs	39	—
Net cash provided by financing activities	66,325	32,533
Effect of exchange rates on cash	(462)	(1,072)
Net decrease in cash	(20,985)	(19,747)
Cash and cash equivalents at beginning of year	28,397	48,144
Cash and cash equivalents at end of period	$ 7,412	$ 28,397
Noncash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expense	$ 445	$ 1,712
Deferred financing costs included in accounts payable and accrued expense	$ —	$ 773
Recognition of earnout liability	$ 58,871	$ —
Recognition of private placement warrant liability	$ 8,140	$ —
Acquisitions of right-of-use assets under operating leases	$ 101	$ 305
Supplemental cash flow information:		
Interest paid on notes payable	$ 1,342	$ 1,578

The accompanying notes are an integral part of these consolidated financial statements.

1. Nature of the Business and Basis of Presentation

Nature of Business

Gelesis Holdings, Inc., or the Company, formerly known as Capstar Special Purpose Acquisition Corp. or "CPSR", is a consumer-centered biotherapeutics company incorporated under the laws of the State of Delaware. The Company aims to transform weight management through proprietary hydrogel technology, inspired by the compositional and mechanical properties of raw vegetables. Since its inception, the Company has devoted substantially all of its efforts to business planning, licensing technology, research and development, commercial activities, recruiting management and technical staff and raising capital and has financed its operations through the issuance of redeemable convertible preferred and common stock, a license and collaboration agreement, supply and distribution agreements, long-term loans, convertible promissory note financings, and government grants.

The Company currently manufactures and markets Plenity® (the "Product"), which is based on a proprietary hydrogel technology. Plenity received a *de novo* clearance from the FDA on April 12, 2019 to aid in weight management when used in conjunction with diet and exercise. In 2020, the Company received its original Conformité Européenne (CE) certificate which allowed Plenity to be marketed as a medical device in Europe as well as rest of the world where CE mark is acceptable. Plenity has been commercially available by prescription in the United States since May 2020. In January 2023, the Company made a 510 (k) submission to the FDA to switch Plenity from prescription ("Rx") to over-the-counter ("OTC").

On July 19, 2021, Gelesis, Inc. (together with its consolidated subsidiaries, "Legacy Gelesis") entered into a Business Combination Agreement (as amended on November 8, 2021 and December 30, 2021, the "Business Combination Agreement") with CPSR, a Delaware corporation and special purpose acquisition company, and CPSR Gelesis Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of CPSR ("Merger Sub"). On January 13, 2022, Legacy Gelesis, CPSR, and Merger Sub consummated the business combination ("Business Combination") pursuant to the terms of the Business Combination Agreement. Pursuant to the Business Combination Agreement, on the closing date, (i) Merger Sub merged with and into Legacy Gelesis (the "Merger"), with Legacy Gelesis as the surviving company in the Merger, and, after giving effect to such Merger, Legacy Gelesis became a wholly-owned subsidiary of CPSR and (ii) CPSR changed its name to "Gelesis Holdings, Inc." (together with its consolidated subsidiaries, "Gelesis Holdings"). The Business Combination, together with the PIPE Investment and the sale of the Backstop Purchase Shares, generated approximately $105 million in gross proceeds and $70.5 million in net proceeds (See Note 3). On January 14, 2022, Gelesis Holdings' common stock and public warrants began trading on the New York Stock Exchange ("NYSE") under the symbols "GLS" and "GLS.W", respectively.

The Business Combination was accounted for as a reverse recapitalization in conformity with accounting principles generally accepted in the United States. Under this method of accounting, CPSR has been treated as the "acquired" company for financial reporting purposes. This determination was primarily based on the Legacy Gelesis' stockholders comprising a relative majority of the voting power of the combined company, the Legacy Gelesis' operations prior to the acquisition comprising the only ongoing operations of Gelesis Holdings, the majority of Gelesis Holdings' board of directors appointment by Legacy Gelesis, and Legacy Gelesis' senior management comprising the entirety of the senior management of Gelesis Holdings. Accordingly, for accounting purposes, the consolidated financial statements of Gelesis Holdings will represent a continuation of the consolidated financial statements of Legacy Gelesis with the Business Combination being treated as the equivalent of Legacy Gelesis issuing stock for the net assets of CPSR, accompanied by a recapitalization. The net assets of CPSR will be stated at historical costs, with no goodwill or other intangible assets recorded.

Going Concern

The audited consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the ordinary course of business. The audited consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company has a history of incurring substantial operating losses and has financed its operations primarily from the issuance of equity, promissory notes, government grants, supply and distribution agreements and collaborations and licensing arrangements. Such operating losses and negative cash flows from operations have continued throughout 2022 and the Company expects they will continue in the foreseeable future. The Company expects its cash on hand as of the date of the consolidated financial statements, proceeds from the initial closing of the 2023 Convertible Senior Secured Notes, and collection of accounts and grants receivable will only be sufficient to meet the Company's obligations into the second quarter of 2023, and not at least twelve months beyond the date of issuance of the consolidated financial statements. In light of current levels of liquidity, the Company has significantly reduced discretionary spending as well as headcount from prior levels, particularly with respect to discretionary sales and marketing activities, manufacturing and supply chain functions, and research and development. These conditions raise substantial doubt about the Company's ability to continue as a going concern and may adversely impact the sale of Plenity.

The Company will need to raise additional capital in future periods to fund its operations. The Company will seek to raise necessary funds through a combination of equity issuances, debt financings, strategic collaborations and licensing arrangements, government grants, or other financing mechanisms. The Company's ability to fund the completion of its ongoing and planned clinical studies, as well as its regulatory and commercial efforts, may be substantially dependent upon whether the Company can obtain sufficient funding at acceptable terms. If adequate sources of funding are not available to the Company, the Company may be required to delay, reduce or eliminate research and development programs, reduce or eliminate commercialization efforts, and reduce its headcount. Additionally, the Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of the full-scope product commercialization in targeted markets, clinical trials and preclinical studies, the impact of the COVID-19 pandemic on the Company's supply chain and results of operations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and development by competitors of technological innovations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") issued by the Financial Accounting Standards Board ("FASB").

The Company consolidates those entities where it has a direct and indirect controlling financial interest based on either a variable interest model or voting interest model. The Company's consolidated financial statements include the accounts of the Company, its two wholly-owned subsidiaries and a variable interest entity ("VIE"), Gelesis S.r.l., in which the Company has a controlling interest and is the primary beneficiary. The noncontrolling interest attributable to the Company's VIE is presented as a separate component from stockholders' deficit in the consolidated balance sheets and as a noncontrolling interest in the consolidated statements of noncontrolling interest, redeemable convertible preferred stock and stockholders' deficit. All intercompany balances and transactions have been eliminated in consolidation. Under the variable interest model, a controlling financial interest is determined based on which entity, if any, has (i) the power to direct the activities of the VIE that most significantly impacts the VIE's economic performance and (ii) the obligations to absorb losses that could potentially be significant to the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE. Management performs ongoing reassessments of whether changes in the facts and circumstances regarding the Company's involvement with a VIE will cause the consolidation conclusion to change. The consolidation status of a VIE may change as a result of such reassessments. Changes in consolidation status are applied prospectively in accordance with U.S. GAAP.

Reclassification of Prior Year Presentation

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations or financial position.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting period. The Company assesses the use of estimates on an ongoing basis; however, actual results could materially differ from those estimates and changes in

estimates are reflected in the results of operations in the period in which they become known.

Subsequent Event(s)

The Company considers events or transactions that occur after the balance sheet date but before the consolidated financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The Company evaluated all events and transactions through the date these consolidated financial statements were filed with the Securities and Exchange Commission ("SEC") or were available to be issued.

Fair Value of Financial Instruments

The guidance in FASB ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"), defines fair value and establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1 – Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 – Valuations based on quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Fair value is a market-based measure considered from the perspective of a market participant rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, the Company's own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. The Company uses prices and inputs that are current as of the measurement date, including during periods of market dislocation. In periods of market dislocation, the observability of prices and inputs may be reduced for many instruments. This condition could cause an instrument to be reclassified from Level 1 to Level 2 or Level 2 to Level 3.

The Company's earnout liability, private placement warrants, and call option liability are recorded at fair value on a recurring basis. The carrying amount of accounts receivable, grants receivable, accounts payable and accrued expenses are considered a reasonable estimate of their fair value, due to the short-term maturity of these instruments. The carrying amount of notes payable is also considered to be a reasonable estimate of the fair value based on the nature of the debt and that the debt bears interest at the prevailing market rate for instruments with similar characteristics. The Company's cash equivalents, and marketable securities are carried at fair value, determined according to the fair value hierarchy described above.

Earnout Liability: In connection with the Business Combination, Legacy Gelesis Equity holders received the right to receive additional common stock upon the achievement of certain earnout targets. As the earnout consideration contains a settlement provision that precludes it from being indexed to the Company's stock, it is classified as a liability held at fair value in accordance ASC 815 and the instrument is adjusted to fair value at each reporting period. In determining the fair value of the earnout liability at inception and on a recurring basis, the Company utilizes the Monte Carlo simulation value model where the fair value of the earnout is the present value of a distribution of potential outcomes on a daily basis over the term of the earnout period.

Private Placement Warrant Liability: The Private Placement Warrants are recognized as liabilities in accordance with ASC 815. Accordingly, the Company recognizes the warrant instruments as liabilities held at fair value and adjusts the instruments to fair value at each reporting period. In determining the fair value of the Private Placement Warrant liability, the Company utilized a modified Monte Carlo simulation value model at inception and on a recurring basis.

One S.r.l. Call Option: In connection with the October 2020 amended agreement with One S.r.l., the Company granted One a contingent call option to buy back the 10% ownership that the Company acquired in the 2019 One Amendment. The One S.r.l. call option was recorded as a liability held at fair value at the date of issuance and is remeasured at each subsequent reporting date with changes in fair value recorded in other income (expense) in the accompanying consolidated statements of operations. Fair value is determined using a Black-Scholes option pricing model.

Convertible promissory notes: The convertible promissory notes issued in conjunction with the Company's bridge financing arrangements from time to time were recognized at fair value at issuance and subsequent changes in fair value were recorded in the accompanying consolidated statements of operations (see Note 12). Fair value of the promissory notes is determined using a multiple scenario-based valuation method. The fair value of the hybrid instrument was determined by calculating the value of the instrument in each scenario "with" the respective conversion feature and "without". The significant inputs used in estimating the fair value of the

convertible promissory notes include the estimated discount rate, expected term, and the outcome probability with respect to each scenario.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents. Cash equivalents, which consist of money market accounts purchased with original maturities of less than 90 days from the date of purchase, are stated at fair value.

Accounts Receivable

The Company extends credit to customers based upon contractual terms or its evaluation of the customer's financial condition.
Customer accounts receivable are stated at amounts due net of applicable discounts and other contractual adjustments as well as an allowance for expected credit losses. The Company assesses the need for an allowance for expected credit losses based upon currently expected credit losses ("CECL") by considering a number of factors, including the length of time trade accounts receivable are past due, the customer's ability to pay its obligation and the condition of the general economy and the industry as a whole. The Company will write off accounts receivable when the Company determines that they are uncollectible. The Company has not historically experienced any collection issues or significant credit losses. Based on historical receipts and collections history, management has determined that an allowance for expected credit losses is not necessary at December 31, 2022 or 2021, respectively.

Government Grants

The Company recognizes grants from governmental agencies in other income on the consolidated statements of operations, gross of the expenditures that were related to the underlying project being co-funded by the grant, when there is reasonable assurance that the Company will comply with the conditions attached to the grant arrangement and payments under the grant will be received. The Company evaluates the conditions of each individual grant as of each reporting period to ensure that the Company has reached reasonable assurance of meeting the conditions of each grant arrangement and that it is expected that the grant payment will be received as a result of meeting the necessary conditions.

The Company has been awarded grants from government agencies in Italy for certain capital expenditures and expenses incurred for research and development work performed under specified programs conducted in Italy. The Company submits qualifying expenses and capital purchases for reimbursement under each specified program, which occurs after the Company has made the capital purchases and/or incurred the research and development costs. The Company records a grant receivable upon incurring such expenses, as approval and reimbursement are considered to be perfunctory once the qualifying program has been approved. Government grants are recognized in the consolidated statements of operations on a systematic basis over the periods in which the Company recognizes the related costs for which the government grant is intended to compensate. Specifically, grant income related to research and development costs is recognized as such expenses are incurred. Research and development costs that were incurred prior to the approval of a qualifying program are recognized as grant income immediately upon approval of the program by the grantor. Grant income related to qualifying capital purchases is recognized in proportion to the depreciation expense incurred on the underlying assets.

Deferred income related to capital purchases for which grant income will be recognized beyond twelve months from the balance sheet date is classified as long-term deferred income on the consolidated balance sheets and amortized to other income, net, over the same life of the related asset.

Inventory

The Company manufactures its own super-absorbent hydrogels used in Plenity® and other product candidates out of its own manufacturing facilities located in Italy. The packaging of the hydrogels is currently outsourced to contract packaging organizations for commercial purposes.

Inventories comprise raw materials, including raw materials for packaging components, work-in-process, and finished goods, which are goods that are available for sale. The Company states inventory at the lower of cost or net realizable value with the cost based on the first-in, first-out method. If the Company identifies excess, obsolete or unsalable items, it writes down its inventory to its net realizable value in the period in which the impairment is identified. These adjustments are recorded based upon various factors related to the product, including the level of product manufactured by the Company, the level of product in the distribution channel, current and projected demand, the expected shelf-life of the product and firm inventory purchase commitments. Significant shipping and handling costs incurred for inventory purchases are included in inventory and costs incurred for product shipments are recorded in cost of goods sold as incurred.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Expenditures for maintenance and repairs are charged to operations as incurred whereas major betterments are capitalized as additions to property and equipment. Depreciation and amortization begin at the time the asset is placed in service, and are recorded using the straight-line method over the estimated useful lives, as follows:

Asset Category	Useful Lives
Computer equipment and software	1 – 3 years
Laboratory and manufacturing equipment	2.5 – 8.3 years
Leasehold improvements	5 – 10 years, or the remaining term of lease, if shorter
Buildings and land improvements	18 – 20 years
Land	Not depreciated

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to the undiscounted expected future cash flows the assets are expected to generate and recognizes an impairment loss equal to the excess of the carrying value over the fair value of the related asset. There were no indicators of impairment as of and for the years ended December 31, 2022 and 2021, respectively.

Intangible Assets

Intangible assets with estimable useful lives, or definite-lived intangibles, are carried at cost and are amortized on a straight-line basis over their estimated useful lives and reviewed for impairment upon certain triggering events. We routinely review the remaining estimated useful lives of definite-lived intangible assets. If we reduce the estimated useful life assumption, the remaining unamortized balance is amortized over the revised estimated useful life.

Redeemable Convertible Preferred Stock

The Company has classified redeemable convertible preferred stock as temporary equity in the consolidated balance sheets due to certain change in control clauses that are outside of the Company's control, including liquidation, sale, or transfer of control of the Company, as holders of the redeemable convertible preferred stock could cause redemption of the shares in these situations. The Company accretes the carrying values of the classes of redeemable convertible preferred stock that are mandatorily redeemable to the redemption values. The Company does not accrete the carrying values of the classes of redeemable convertible preferred stock that are not mandatorily redeemable to the redemption values since a liquidation event, sale, or transfer is not considered probable. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only if and when it becomes probable that such a liquidation event will occur.

Noncontrolling Interests

The Company recognizes noncontrolling interest related to VIEs, in which the Company is the primary beneficiary, as temporary equity in the consolidated financial statements separate from the shareholders' equity. Changes in the shareholders' ownership interest in a subsidiary that do not result in deconsolidation are treated as equity transactions if the parent entity retains its controlling financial interest. In addition, when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary will be initially measured at fair value and the difference between the carrying value and fair value of the retained interest will be recorded as a gain or loss.

Leases

The Company determines if an arrangement is a lease at contract inception under ASC 842 – *Leases*. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. The Company recognizes operating lease assets and liabilities at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. As the discount rate implicit in the leases was typically not readily determinable, the Company utilized the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment, the incremental borrowing rate (IBR).

The Company has elected to apply the practical expedient to account for lease and non-lease components as a single lease component for new and modified leases commencing after adoption election. The Company has also elected not to recognize leases with an initial

term of 12 months or less on the consolidated balance sheets, instead, those lease payments are recognized in the consolidated statements of operations on a straight-line basis over the lease term.

Revenue Recognition

Product Revenue

The Company commercializes Plenity in the U.S. markets principally through synergistic partnerships with online pharmacies and telehealth providers, which in turn sell Plenity directly to patients based on prescriptions. Outside the U.S., the Company primarily seeks collaborations with strategic partners to market Plenity and obtain necessary regulatory approvals as necessary.

Product revenue is recognized by the Company in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services when the customer obtains control of the product, which occurs at a point in time, when the product is received by the Company's customers.

Reserves for Variable Consideration

Revenues from product sales are recorded as product revenue at the net sales price (transaction price), which includes estimates of variable consideration that are reimbursable to customers for which reserves are established and which result from (a) shipping charges to end-users, (b) pharmacy dispensing and platform fees, (c) merchant and processing fees, (d) promotional discounts offered by the Company to end-users, and (e) reserves for expected product quality returns. These reserves for contractual adjustments are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than the customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which the Company is entitled based on the terms of the contract(s). The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. The Company has no plan to seek government or commercial payor reimbursements in the US or the overseas markets. Therefore, reserves for variable consideration do not contain any components related to government and payor rebates or chargebacks.

Product Returns

The Company generally does not accept customer returns, except for product quality related cases. The Company evaluates quality related returns and adjusts the corresponding product warranty reserves and liabilities at least quarterly and at the end of each reporting period.

License and Collaboration Revenues

The Company recognizes revenue from product sales and collaboration arrangements in accordance with ASC 606, *Revenue from Contracts with Customers* (“ASC 606”). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it expects to be entitled to in exchange for the goods or services it transfers to the customer.

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available, and whether the goods or services are integral or dependent to other goods or services in the contract. For performance obligations which consist of the Company’s materials, shipping and distribution activities occur prior to the transfer of control of the Company’s materials and are considered activities to fulfill the Company’s promise to deliver goods to the customers.

The Company has entered and anticipates to enter future license, collaboration and/or distribution agreements, which are within the scope of ASC 606, to manufacture and commercialize product(s). The terms of these agreements typically contain multiple promises or obligations, which may include: (i) manufacturing and supply of covered products, and (ii) regulatory support activities to be provided to the collaboration partner relating to the covered product(s). Payments to the Company under these agreements may include payments based upon the achievement of certain milestones and royalties on any resulting net product sales.

The Company first evaluates collaboration arrangements to determine whether the arrangement (or part of the arrangement) represents a collaborative arrangement pursuant to ASC Topic 808, *Collaborative Arrangements,* based on the risks and rewards and activities of the parties pursuant to the contractual arrangement. The Company accounts for collaborative arrangements (or elements within the contract that are deemed part of a collaborative arrangement), which represent a collaborative relationship and not a customer relationship, outside the scope of ASC 606. The Company's collaborations primarily represent revenue arrangements. The Company uses judgment to determine whether milestones or other variable consideration, except for sales-based royalties, should be included in the transaction price. The transaction price is allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. There were no performance obligations to be satisfied over time for recognition purposes as of and for the years ended December 31, 2022 and 2021, respectively.

Amounts received prior to revenue recognition are recorded as deferred income. Amounts expected to be recognized as revenue within the year following the balance sheet date are classified as current portion of deferred income in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as deferred income, net of current portion. Amounts recognized as revenue, but not yet received or invoiced are generally recognized as contract assets.

Cost of goods sold

Cost of goods sold includes the cost of manufacturing our proprietary superabsorbent hydrogels for Plenity for which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management and quality assurance. Expenses from royalty agreements on net product sales are also recognized as a component of cost of goods sold during the period in which the associated revenues are recognized. A portion of depreciation with respect to property and equipment directly utilized in manufacturing Plenity units is recognized as a component of cost of goods sold over the depreciable life of the asset.

If the Company identifies excess, obsolete or unsalable inventory items, it writes down these to their net realizable values in the period in which the impairment is identified with corresponding charges to cost of goods sold in the consolidated statements of operations. These adjustments are recorded based upon various factors related to the product, including the level of product manufactured by the Company, the level of product in the distribution channel, current and projected demand, the expected shelf-life of the product and firm inventory purchase commitments.

Selling, General and Administrative Costs

Selling, general and administrative costs are expensed as incurred. Selling, general and administrative costs include sales and marketing costs incurred as a result of the commercialization of the Company’s products, payroll and personnel expense, stock-based compensation expense, and costs of programs and infrastructure necessary for the general conduct of the Company’s business.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include payroll and personnel expense, stock-based compensation expense, consulting costs, external contract research and development expenses, as well as depreciation and utilities. Prepaid research and development costs are deferred and amortized over the service period, as the services are provided.

Stock-Based Compensation

The Company’s stock-based compensation consist primarily of stock options and restricted stock units. The measurement date for share-based awards is the date of grant, and stock-based compensation costs are recognized as expense over the respective requisite service periods, which are typically the vesting period. The fair value of each stock option grant is estimated as of the date of grant using the Black-Scholes option-pricing model that requires management to apply judgment and make estimates, including:

- *exercise price:* The exercise price is the fair market value on grant date, which shall mean the closing sale price of common stock, as reported on such market on that date (or if there are no market quotations for such date, the determination shall be made by reference to the last date preceding such date for which there are market quotations);
- *expected volatility:* As the Company was previously a privately-owned company, there is not sufficient historical volatility for the expected term of the options. Therefore, the Company used an average historical share price volatility based on an analysis of reported data for a peer group of comparable companies for which historical information is available. For these analyses, the Company selects companies with comparable characteristics to itself including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of its stock-based awards. The Company intends to consistently apply this process using representative companies until a sufficient amount of historical information regarding the volatility of its own share price becomes available;
- risk-free interest rate, which is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption;
- expected term, which is calculated using the simplified method, as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment,* as the Company has insufficient historical information regarding its stock options to provide a basis for an estimate. Under this approach, the weighted-average expected life is presumed to be the average of the contractual term of ten years and the weighted-average vesting term of the stock options, taking into consideration multiple vesting tranches;
- dividend yield, which is zero based on the fact that the Company never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Stock-based compensation costs for non-employees are recognized as expense over the vesting period. Stock-based compensation expense is classified in the consolidated statements of operations based on the function to which the related services are provided. Forfeitures are recorded as they occur.

Income Taxes

The consolidated financial statements reflect provisions for federal, state, local and foreign income taxes. Deferred tax assets and liabilities are recognized based on temporary differences between the financial reporting and income tax basis of assets and liabilities using rates anticipated to be in effect when such temporary differences reverse. A change in tax rates is recognized in income in the period of the enactment date. A valuation allowance against net deferred tax assets is required if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company also assesses the probability that the positions taken or expected to be taken in its income tax returns will be sustained by taxing authorities. A "more likely than not" (more than 50%) recognition threshold must be met before a tax benefit can be recognized. Tax positions that are more likely than not to be sustained on examination by the taxing authorities, based on the technical merits of the position, are reflected in the Company's consolidated financial statements. Tax positions are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement with a taxing authority that has full knowledge of all relevant information. The difference between the benefit recognized for a position and the tax benefit claimed on a tax return is referred to as an unrecognized tax benefit. Potential interest and penalties associated with such uncertain tax positions are recorded as a component of income tax expense.

Foreign Currency Translation

The financial statements of each of the Company's subsidiaries with a functional currency other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders' equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income (loss) in stockholders' equity. Foreign currency transaction gains and losses are included in other (expense) income, net in the results of operations.

Concentrations of Credit Risk and Off -Balance-Sheet Risk

The Company has no significant off-balance-sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash and cash equivalents, investments, accounts receivable and unbilled account receivables.

The Company's cash balances, trade receivables, and grants receivable subject the Company to significant concentrations of credit risk. Periodically, the Company maintains deposits in government insured financial institutions in excess of government insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk on cash. The Company's grants receivable are due from government agencies, which the Company believes to have high credit quality. The Company has a limited number of commercial customers. The Company monitors the creditworthiness of customers to whom it grants credit terms and has not experienced any credit losses.

Earnings (Loss) per Share

The Company computes basic earnings (loss) per share by dividing income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding. During periods of income, the Company allocates participating securities a proportional share of income determined by dividing total weighted average participating securities by the sum of the total weighted average common shares and participating securities (the "two-class method"). The Company's restricted stock and various series of preferred stock participate in dividends declared by the Company and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, the Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. The Company computes diluted earnings (loss) per share after giving consideration to the dilutive effect of stock options and warrants that are outstanding during the period, except where such non-participating securities would be anti-dilutive.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer. The Company and the chief operating decision maker view the Company's operations and manage its business as one operating segment. Geographically, the Company operates out of the U.S. and Italy. The corporate headquarters including the core functions of sales and marketing, medical affairs, research and development and general and administrative are located in the U.S., while substantially all of the Company's manufacturing facilities and operations physically reside in Italy.

Effect of Recently Issued Pronouncements

In January 2020, the FASB issued ASU 2020-01, *Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)*. The amendments in ASU 2020-01 clarify certain interactions between the guidance to account for certain equity securities under Topic 321, the guidance to account for investments under the equity method of accounting in Topic 323, and the guidance in Topic 815, which could change how an entity accounts for an equity security under the measurement alternative or a forward contract or purchased option to purchase securities that, upon settlement of the forward contract or exercise of the purchased option, would be accounted for under the equity method of accounting or the fair value option in accordance with Topic 825, Financial Instruments. These amendments improve current GAAP by reducing diversity in practice and increasing comparability of the accounting for these interactions. The amendments in this update are effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years.

The Company adopted ASU 2020-01 as of January 1, 2022 and the adoption of this standard did not have a material impact on the consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. The amendments in ASU 2020-06 include guidance on convertible instruments and the derivative scope exception for contracts in an entity's own equity and simplifies the accounting for convertible instruments which include beneficial conversion features or cash conversion features by removing certain separation models in Subtopic 470-20. Additionally, ASU 2020-06 will require entities to use the "if-converted" method when calculating diluted earnings per share for convertible instruments. The amendments in this update are effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years.

The Company adopted ASU 2020-06 as of January 1, 2022 and the adoption of this standard did not have a material impact on the consolidated financial statements and related disclosures.

In May 2021, the FASB issued ASU 2021-04 , *Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. The guidance in ASU 2021-04 requires the issuer to treat a modification of an equity-classified written call option that does not cause the option to become liability-classified as an exchange of the original option for a new option. This guidance applies whether the modification is structured as an amendment to the terms and conditions of the option or as termination of

the original option and issuance of a new option. The amendments in this update are effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years.

The Company adopted ASU 2021-04 as of January 1, 2022 and the adoption of this standard did not have a material impact on the consolidated financial statements and related disclosures.

3. Business Combination and Reverse Recapitalization

As discussed in Note 1, on January 13, 2022, the Company consummated the Business Combination pursuant to the Business Combination Agreement with CPSR dated July 19, 2021, as amended on November 8, 2021 and December 30, 2021. Concurrently with the execution of the Business Combination Agreement, CPSR entered into subscription agreements with certain investors (the "PIPE Investors"). Pursuant to the subscription agreements, the PIPE Investors purchased an aggregate of 9,000,000 shares of CPSR's Class A common stock (the "PIPE Investment") in a private placement at a price of $10.00 per share for an aggregate purchase price of $90.0 million. The PIPE Investment was consummated in connection with the closing. On December 30, 2021, CPSR entered into a backstop agreement (the "Backstop Agreement") with certain investors (the "Backstop Investors"). Pursuant to the Backstop Agreement, the Backstop Investors purchased an aggregate of 744,217 shares of CPSR's Class A common stock ("Backstop Purchase Shares") in a private placement at a price of $10.00 per share for an aggregate purchase price of $7.4 million. Additionally, CPSR issued the Backstop Investors 1,983,750 shares of CPSR Class A common stock as additional consideration. The Backstop Agreement was consummated in connection with the closing.

The Business Combination was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, CPSR, who was the legal acquirer, was treated as the acquired company for financial reporting purposes. Accordingly, the Business Combination was treated as the equivalent of Gelesis issuing stock for the net assets of CPSR, accompanied by a recapitalization.

In connection with the Business Combination, aggregate transaction costs of $37.2 million were incurred, consisting of underwriting, legal, and other professional fees, of which $22.3 million were direct transaction costs incurred by CPSR, $9.5 million were assumed liabilities from CPSR, and $5.4 million were transaction costs incurred by Legacy Gelesis. Of the Legacy Gelesis transaction costs, $2.7 million was allocated to the Earnout Shares and expensed upon the Closing, based on the relative fair value of the Earnout Shares as compared to the other newly issued instruments as part of the Business Combination. The remaining transaction costs were recorded within additional paid-in capital on the accompanying consolidated financial statements.

The following table summarizes the net proceeds from the Business Combination, as reconciled to the accompanying consolidated statements of noncontrolling interest, redeemable convertible preferred stock and stockholder's equity (deficit) and the consolidated statements of cash flows (in thousands):

		Amount
Cash - CPSR trust and cash (net of redemptions)	$	7,558
Cash - PIPE Investment		90,000
Cash - Backstop Agreement		7,442
Gross proceeds	$	105,000
Less: transaction costs, advisory fees and liabilities paid		(34,522)
Net proceeds from the Business Combination	$	70,478

Immediately prior to closing of the Business Combination, Legacy Gelesis common stock was split according to the exchange ratio of 2.59, which was determined pursuant to the Business Combination Agreement and based on Legacy Gelesis' implied price per share prior to the Business Combination. Upon closing of the Business Combination, holders received shares of common stock of the Company on a one-to-one basis. For periods prior to the Business Combination, in the accompanying consolidated financial statements, the reported share and per share amounts have been retroactively converted ("Retroactive Application of Recapitalization") by applying the exchange ratio. The consolidated assets, liabilities and results of operations prior to the Business Combination are those of Legacy Gelesis.

Immediately prior to the closing of the Business Combination, Legacy Gelesis redeemable convertible preferred stock converted into Legacy Gelesis common stock and was subsequently split according to the exchange ratio of 2.59. Upon closing of the Business Combination, holders received shares of common stock of the Company on a one-to-one basis.

Immediately prior to the closing of the Business Combination, Legacy Gelesis stock options and restricted stock units ("RSU") were split according to the exchange ratio of 2.59. Upon closing of the Business Combination, holders of Legacy Gelesis stock options

received a stock option to purchase shares of the Company's common stock on a one-to-one basis and holders of Legacy Gelesis RSUs received RSUs of the Company on a one-to-one basis.

Immediately prior to the closing of the Business Combination, Legacy Gelesis redeemable preferred stock warrants were converted into Legacy Gelesis common warrants and were subsequently split according to the exchange ratio of 2.59. Upon closing of the Business Combination, holders received rollover common stock warrants of the Company on a one-to-one basis.

Immediately prior to the closing of the Business Combination, Legacy Gelesis common warrants were split according to the exchange ratio of 2.59. Upon closing of the Business Combination, holders received rollover common stock warrants of the Company on a one-to-one basis.

The number of shares of common stock issued and outstanding immediately following the consummation of the Business Combination was as follows:

	Common Stock
CPSR Public Stockholders	755,223
CPSR Sponsor Stockholders	4,916,250
Total CPSR Stockholders	5,671,473
Common stock issued to Gelesis Legacy Equityholders	54,814,847
Common stock issued to PIPE Investors and Backstop Agreement	11,727,967
Total common stock immediately after Closing	72,214,287

Earnout Shares

In addition, each holder of Legacy Gelesis common stock, Legacy Gelesis options and Legacy Gelesis warrants will receive a pro rata portion of up to 23,482,845 restricted earnout shares of Gelesis Holding's common stock, which will be issued and vest in equal thirds if the trading price of the Company's common stock is greater than or equal to $12.50, $15.00 and $17.50, respectively, for any twenty (20) trading days within any thirty (30)-trading day period on or prior to the date that is five years following the close of the Business Combination and will also vest in connection with any change of control transaction with respect to the Company if the applicable thresholds are met in such change of control transaction during the earnout period (each a "Triggering Event").

The Company determined 18,758,241 earnout shares are considered a contingent consideration arrangement in accordance with ASC 815, and recorded a liability upon the closing of the Business Combination of $58.9 million (see Note 14). The Company determined the remaining 4,724,604 earnout shares, which pertain to Legacy Gelesis equity awards, are incremental compensation in accordance with ASC 718 and equity classified. The total fair value of incremental compensation cost at the close of Business Combination was $14.8 million which will be expensed according to the vesting terms of the original underlying equity awards. The total incremental compensation cost, pertaining to Legacy Gelesis equity awards which had previously vested, was $11.4 million, of which $7.0 million and $4.4 million was recognized immediately following the close of the Business Combination as expense in selling, general and administrative expense and research and development expense, respectively, in the accompanying consolidated statements of operations.

Public Warrants and Private Placement Warrants

Upon the closing of the Business Combination, the Company assumed 13,800,000 Public Warrants and 7,520,000 Private Placement Warrants. The Company determined the Public Warrants qualified as equity instruments in accordance with ASC 815 and reclassified the Public Warrants from liability to equity classification and the carrying value of $7.1 million was transferred to APIC on the accompanying consolidated balance sheets. The Company determined the Private Placement Warrants met the definition of a liability under ASC 815 and recorded a liability reflecting the fair value of the Private Placement Warrants of $8.1 million. See Note 13 and Note 15 for further information on the Private Placement and Public Warrants, respectively.

4. Fair Value Measurements

Assets and liabilities that are measured at fair value on a recurring basis, and the level of the fair value hierarchy utilized to determine such fair values, consisted of the following at December 31, 2022 (in thousands):

		Fair Value Measurements		
	Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Asset:				
Interest rate swap contract (see Note 12)	$ 800	$ —	$ 800	$ —
Liabilities:				
Convertible promissory notes (see Note 12)	27,403	—	—	27,403
Earnout liability (see Note 14)	563	—	—	563
Private placement warrant liability (see Note 13)	130	—	—	130
One S.r.l. call option (see Note 11)	674	—	—	674
Total liabilities measured at fair value	$ 28,770	$ —	$ —	$ 28,770

Liabilities that are measured at fair value on a recurring basis, and the level of the fair value hierarchy utilized to determine such fair values, consisted of the following at December 31, 2021 (in thousands):

		Fair Value Measurements		
	Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities:				
Convertible promissory notes (see Note 12)	$ 27,128	$ —	$ —	$ 27,128
Legacy Gelesis preferred stock warrants (see Note 13)	15,821	—	—	15,821
One S.r.l. call option (see Note 11)	2,416	—	—	2,416
Total liabilities measured at fair value	$ 45,365	$ —	$ —	$ 45,365

The following table presents a summary of the changes in the fair value of the Company's Level 3 financial instruments during the years ended December 31, 2022 and 2021, respectively (in thousands):

	Convertible Promissory Notes	Legacy Gelesis Redeemable Preferred Stock Warrants Liabilities	One S.r.l. Call Option	Earnout Liability	Private Placement Warrant Liability
Balance at December 31, 2020	$ —	$ 12,099	$ 1,545	$ —	$ —
Exercise of warrants	—	(3,924)	—	—	—
Issuance of convertible promissory notes	27,000	—	—	—	—
Changes in fair value	128	7,646	1,024	—	—
Foreign currency translation adjustment	—	—	(153)	—	—
Balance at December 31, 2021	$ 27,128	$ 15,821	$ 2,416	$ —	$ —
Assumed upon Business Combination	—	—	—	—	8,140
Recognized upon Business Combination	—	—	—	58,871	—
Issuance of convertible promissory notes	25,000	—	—	—	—
Changes in fair value	2,559	926	(1,462)	(58,308)	(8,010)
Foreign currency translation adjustment	—	—	(280)	—	—
Conversion and exchange upon Business Combination	—	(16,747)	—	—	—
Settlement	(27,284)	—	—	—	—
Balance at December 31, 2022	$ 27,403	$ —	$ 674	$ 563	$ 130

There were no transfers into or out of level 3 instruments and/or between level 1 and level 2 instruments during the years ended December 31, 2022 and 2021, respectively. The fair value of the interest rate swap contract is determined based on quoted prices in markets that are not active for which significant inputs are observable either directly or indirectly and thus represents a level 2 measurement. The fair value measurement of the convertible promissory notes, Legacy Gelesis preferred stock warrant liability, One S.r.l. call option liability, earnout liability and private placement warrant liability utilized inputs not observable in the market and thus represents a Level 3 measurement.

5. Product Revenue and Reserve and Allowances

The Company sells the Product principally to a limited number of customers consisting of telemedicine and online pharmacies, that in turn resell the Product to consumers.

Revenue for the years ended December 31, 2022 and 2021 consisted of the following (in thousands):

	Years Ended December 31,	
	2022	2021
Roman Health Pharmacy LLC	$ 19,957	$ 9,630
GoGoMeds	5,601	$ 1,437
CMS	—	118
Total	$ 25,558	$ 11,185

Roman Health Pharmacy LLC ("Ro")

In August 2019, the Company entered into a two-year exclusive supply and distribution agreement with Ro, giving Ro exclusive distributor rights to sell the Product via telehealth platforms in the United States. The Company began shipping products to Ro in May 2020 on consignment basis, under which the Company retained legal title to the units shipped on consignment and recognized revenue based on units subsequently shipped by Ro to end-users.

In January 2021, the Company amended and restated the agreement with Ro ("Ro agreement"). Pursuant to the amended and restated Ro agreement, the Company received $10.0 million of cash as a pre-buy commitment for Product which was recorded to current deferred income in the accompanying consolidated balance sheets. Additionally, the amended and restated agreement ended the consignment arrangement with Ro and the Company no longer retained control of any units shipped to Ro under the amended terms. Henceforth, all products shipped to Ro are immediately recognized as revenue upon the transfer of physical control.

In July 2021, the Company executed a second amended and restated agreement with Ro, under which the Company received $30.0 million of cash as a second pre-buy commitment for the Product, which was recorded to current deferred income in the accompanying

consolidated balance sheets. Additionally, the Company extended Ro's exclusive period by approximately one year through July 1, 2023. Upon expiration of the exclusive period as amended, the exclusive right and license under the agreement shall automatically convert to non-exclusive for the remainder of term of the agreement unless further extended. The agreement may be terminated by mutual agreement after the exclusive period expired.

On June 14, 2022, the Company entered into a third Amended and Restated Supply and Distribution Agreement with Ro, pursuant to which the parties amended their previous agreement that granted Ro exclusive telehealth distributor rights to sell Plenity in the United States in the mail order/online pharmacy channel. Pursuant to the amendment, the Company received $15.0 million in cash from Ro as a pre-buy commitment to purchase units of Plenity, which was recorded to deferred income upon receipt in the accompanying consolidated balance sheets.

During the years ended December 31, 2022 and 2021, the Company recognized net product revenue of $20.0 million and $9.6 million, respectively, under the Ro agreement as amended. At December 31, 2022 and December 31, 2021, the Company recorded current deferred income with respect to the Ro agreement aggregated $25.9 million and $31.0 million, respectively, in the accompanying consolidated balance sheets.

GoGoMeds ("GGM")

In February 2020, the Company entered into a two-year exclusive distribution agreement with GGM, giving GGM exclusive distributor rights to all online and mail orders generated in the United States, except those via telehealth. GGM submits purchase orders as needed to Cardinal Health and Cardinal Health ships to GGM. Once GGM has accepted the delivered Product, GGM takes control of the Product and the Company is entitled to payment. The Company began shipping products to GGM in May 2020. The Company recognizes revenue based on units shipped to GGM and upon transfer of physical control.

During the years ended December 31, 2022 and 2021, the Company recognized $5.6 million and $1.4 million net product revenue, respectively. At December 31, 2022 and December 31, 2021, the Company recorded an accounts receivable with respect to GGM aggregated $1.1 million and $0.7 million, net of reserves and allowances, respectively, in the accompanying consolidated balance sheets.

CMS Bridging DMCC ("CMS")

In June 2020, the Company and CMS Bridging DMCC ("CMS") entered into a set of licensing, collaboration, and investing agreements ("CMS Agreements") involving the license of the Company's intellectual property ("IP") to CMS in Singapore and Greater China (the "CMS Territory") and governing the supply of product from the Company to CMS for sale in the CMS Territory, together with an agreement for CMS to invest in the Company's Series Growth 3 & 4 Preferred Shares.

Under the terms of the CMS Agreement, the Company granted CMS an exclusive, transferable, sub-licensable, and royalty-bearing license of the Company's IP to develop, import, register, manufacture, and commercialize the Product, whether through online sales channels or offline sales channels during the term of the agreement. The agreement can be terminated earlier by mutual agreement of the parties. In accordance with the CMS Agreement, all legal and beneficial ownership of (i) all IP rights relating to the Products (including any data generated from the use of the Products and other improvements) and (ii) all of the information provided or generated under the agreement or otherwise related to the Products shall both ultimately belong to and remain vested with the Company. CMS must purchase the Product from the Company at a markup of the Company's cost of goods sold.

As consideration for the rights and licenses granted by the Company to CMS under the agreement, CMS paid the Company a one-time, non-refundable and non-creditable upfront fee of $15.0 million and is required to pay a one-time, non-refundable, and non-creditable milestone payment of $5.0 million within thirty days after the earlier of (i) the approval of marketing authorization as a prescription product by the National Medical Products Administration, and (ii) the fifth anniversary of the agreement's effective date. The CMS Agreement also contains commercial milestones due to the Company based on the achievement of annual net product revenue thresholds in the CMS Territory. Additionally, CMS shall pay the Company royalties on net sales of all products in the CMS Territory commencing January 1, 2022 through the expiration date of the agreement.

The Company determined that the only performance obligation present was the licensing of the Product in the CMS Territory. The transactions price consisted of the $15.0 million upfront payment and the discounted time-based milestone of $3.7 million with the difference of $1.3 million accreted as interest income over five years with the remaining balance being accreted in full upon the approval of the marketing authorization as a prescription product if achieved prior to the end of the five years. The IP license granted to CMS represents a right to use the IP and therefore was recognized at a point in time, which was determined to be the effective date of the agreements.

On August 4, 2022, the Company amended the CMS Agreement, under which the one-time regulatory approval milestone payment of $5.0 million provided for in the original agreement became immediately payable. Additionally, the amendment expands the CMS Territory to include Brunei, Myanmar, Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Thailand and Vietnam and

provides that the minimum annual royalty term for CMS Territory will commence January 2024 (rather than January 2022 as previously provided under the original CMS Agreement). The Company also issued to CMS a warrant to purchase up to 400,000 shares of common stock, par value $0.0001 per share, at an exercise price of $0.01 per share. The discounted one-time regulatory approval milestone, which had a carrying value of $4.2 million and $4.1 million as of August 4, 2022 and December 31, 2021, was fully collected upon execution of the CMS amendment.

As a result of the 2022 amendment, during the year ended December 31, 2022, the Company recognized licensing revenue of $0.2 million representing incremental consideration received by the Company for the additional territories granted to CMS in the accompanying consolidated statement of operations, and $0.6 million of additional paid-in capital representing the fair value of the common stock warrants in the accompanying consolidated balance sheet. The sales-based royalties and other commercial milestones will only be recognized in the periods in which the applicable subsequent sales occur.

Reserves and Allowances

The following table summarizes the activity in the product revenue reserve and allowances during the years ended December 31, 2022 and 2021 (in thousands):

	2022	2021
Balance at January 1,	$ 82	$ 14
Provision related to product sales	1,889	522
Credits and payments made	(1,949)	(454)
Balance at December 31,	$ 22	$ 82

At December 31, 2022 and 2021, product related reserve and allowances comprised solely contractual adjustments owed to the Company's telehealth and online pharmacy partners, which were netted to accounts receivable in the Company's consolidated balance sheets for the year. Through December 31, 2022, there had been no product related reserves or allowances owed to other parties, including the federal and state governments or their agencies.

6. Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	$ 9,549	$ 8,074
Work in process	4,695	2,643
Finished goods	5,955	2,786
Inventories, gross	20,199	13,503
Less: inventory reserves	(13,334)	—
Total inventories	$ 6,865	$ 13,503

In January 2023, the Company submitted a 510(k) application with the FDA to change the classification of Plenity from prescription only to OTC, which, if cleared by the FDA, would make Plenity available to consumers without the need for a prescription. If Plenity is approved by the FDA as an OTC weight management aid, a portion of finished goods and raw material inventories with Rx labeling and marking information would become obsolete. Additionally, finished goods and work-in-process inventories with expiration dates ranging between July 2023 and March 2024 are subject to shelf-life limitations.

As of December 31, 2022, the Company estimated that approximately $5.0 million finished goods, $4.5 million work-in-progress and $3.8 million raw material inventories wouldn't be sold or utilized. Therefore, the Company recorded an aggregate $13.3 million excess and obsolescence inventory reserves as a component of inventories on the accompanying consolidated balance sheet as of December 31, 2022.

7. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2022	2021
Prepaid expenses	$ 314	$ 982
Prepaid insurance	268	55
Prepaid manufacturing expenses	—	2,624
Prepaid contract research costs	189	262
Research and development tax credit	567	579
Value added tax receivable	2,036	5,633
Deferred financing costs	—	3,855
Income tax receivable	203	213
Investment tax credit	1,050	—
Prepaid expenses and other current assets	$ 4,627	$ 14,203

8. Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	December 31,	
	2022	2021
Laboratory and manufacturing equipment	$ 29,944	$ 28,101
Land and buildings	10,673	10,404
Leasehold improvements	1,525	1,614
Computer equipment and software	811	463
Capitalized software	232	228
Construction in process	24,287	22,097
Property and equipment – at cost	67,472	62,907
Less accumulated depreciation	(8,137)	(4,392)
Property and equipment – net	$ 59,335	$ 58,515

The Company owns and operates commercial manufacturing and research and development facilities in Italy, including a 51,000 square foot facility, which the Company expects to further expand to an 88,600 square foot facility, as well as approximately 12 acres of land, where the Company owns land to develop an additional 207,000 square foot facility. Both facilities are near the Town of Lecce in the Puglia region of Italy. Property and equipment classified as construction in process at December 31, 2022 and December 31, 2021 are related to the development of manufacturing lines that have not yet been placed into service at December 31, 2022 and December 31, 2021, respectively.

Depreciation expense was approximately $3.2 million and $1.5 million for the years ended December 31, 2022 and 2021, respectively.

9. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued payroll and related benefits	$ 1,550	$ 1,384
Accrued professional fees and outside contractors (including due to related party of $153 and $60, respectively)	3,521	4,359
Accrued property, plant and equipment additions	378	1,257
Accrued inventory and manufacturing expense	1,020	128
Unpaid portion of One S.r.l. equity acquisition (see Note 11)	2,656	5,604
Tax payables	543	145
Deferred legal fees	738	738
Accrued interest	62	45
Total accrued expenses	$ 10,468	$ 13,660

10. Other Long-Term Liabilities

Other long-term liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Long-term tax liabilities	$ 224	$ 182
One S.r.l. call option (see Note 11)	674	2,416
Contingent loss for research and development tax credits	—	2,990
Total other long-term liabilities	$ 898	$ 5,588

11. Significant Agreements

Puglia 1 Grant

In May 2020, the Company was awarded a grant by the Puglia region of Italy as an incentive to manufacture and carry out research and development activities in Italy ("PIA 1 Grant"). with the key underlying activity being the development of the commercial facility to expand production capacity for the Product. The PIA 1 Grant provides funding of up to €5.3 million (approximately $5.7 million at December 31, 2022) as reimbursement for certain facility and equipment investments in the Company's manufacturing facility in Calimera, Italy, and up to €3.9 million (approximately $4.2 million at December 31, 2022) as reimbursement for certain research and development expenditures over a three-year period. The Company is required to adhere to standard workplace safety regulations and local laws in Italy and is not permitted to physically move the reimbursed assets from the Puglia region for five years from the project completion date of May 2023. The Company has concluded that income recognition is appropriate as it is reasonably assured that it will comply with all the conditions of the grant and the proceeds from the grant for costs incurred to date will be received.

The following table represents amounts recognized on the consolidated statements of operations for the years ended December 31, 2022 and 2021 and on the consolidated balance sheets at December 31, 2022 and 2021 in relation to the Puglia 1 Grant (in thousands):

	December 31,	
	2022	2021
PIA 1 Grant income	$ 756	$ 465
Income attributable to R&D expense	71	220
Income attributable to investments in facilities and equipment	694	246
Proceeds	6,261	—
Grant receivable	3,237	5,439
Deferred income	5,001	6,449
Current portion of deferred income	771	858

Puglia 2 Grant

In November 2020, the Company was awarded a second grant by the Puglia region of Italy as an incentive to manufacture and carry out research and development activities in Italy ("PIA 2 Grant"), with the key underlying activity being the development of a second manufacturing line at the commercial facility to expand production capacity for the Product, and research and development activities targeting new gastrointestinal health indications. The PIA 2 Grant provides funding of up to €3.3 million (approximately $3.5 million at December 31, 2022) as reimbursement for certain facility and equipment investments in the Company's manufacturing facility in Calimera, Italy, and up to €8.3 million (approximately $8.9 million at December 31, 2022) as reimbursement for certain research and development expenditures over a three-year period. The Company is required to adhere to standard workplace safety regulations and local laws in Italy and is not permitted to physically move the reimbursed assets from the Puglia region for five years from the project completion date of November 2023. The Company has concluded that income recognition is appropriate as it is reasonably assured that it will comply with all the conditions of the grant and the proceeds from the grant for costs incurred to date will be received.

The following table represents amounts recognized on the consolidated statements of operations for the years ended December 31, 2022 and 2021 and on the consolidated balance sheets at December 31, 2022 and 2021 in relation to the Puglia 2 Grant (in thousands):

	December 31,	
	2022	2021
PIA 2 Grant Income	$ 1,411	$ 1,054
Income attributable to R&D expense	1,411	1,135
Income attributable to investments in facilities and equipment	—	—
Proceeds	1,751	1,855
Grant receivable	122	3,631
Long-term grant receivable	4,732	—
Deferred income	3,502	3,711
Current portion of deferred income	420	445

One S.r.l. ("One") Amended Patent License and Assignment Agreement

In October 2008 and December 2008, the Company entered into a patent license and assignment agreement and master agreement with One, the original inventor and owner of the Company's core patents and a related party to the Company (see Notes 19 and 20), to license and subsequently purchase certain intellectual property to develop hydrogel-based product candidates. In December 2014, the Company amended and restated the patent license agreement and the master agreement into a single agreement, referred to as the amended and restated master agreement (the "2014 One Amendment"). The amended and restated master agreement would remain in effect until the expiration of the last patents covered by the agreement or until all obligations under the amended and restated master agreement with respect to payments have terminated or expired.

In June 2019, the Company further amended and restated the master agreement with One (the "2019 One Amendment"). Under the 2019 One Amendment, the Company eliminated certain future commercial milestone obligations and received a reduction in the percentage of royalties the Company was required to pay on future net sales. In return, One received additional consideration consisting of new future milestones upon the commercial success of new medical indications and a contingently issuable warrant for redeemable convertible preferred stock. Additionally, the Company acquired a 10% equity interest in One in exchange for cash consideration.

The Company accounted for the reduction in royalties the Company is required to pay on future net revenues that resulted from the 2019 One Amendment as an intangible asset under ASC 350, Intangibles – Goodwill and Other, which shall be amortized over its useful life, which was determined to be the earliest expiration of patents related to the underlying intellectual property in November 2028. The Company accounted for the acquisition of the 10% equity interest in One under ASC 323, Investments – Equity Method and Joint Ventures. The Company initially allocated consideration in the June 2019 transaction on a relative fair value basis in the following manner (in thousands):

Consideration	
Cash	$ 12,668
Warrants for redeemable convertible preferred stock	4,706
Fair value of total consideration	$ 17,374
Assets acquired at relative fair value	
Intangible asset related to reduction in royalty	$ 15,564
Equity-method investment	1,810
Total assets acquired	$ 17,374

The Company accounted for tax impact of the acquisition of the intangible asset under ASC 740, Income Taxes, which resulted in the recognition of a deferred tax liability of $5.8 million, to account for the book-to-tax basis difference, that was applied to the initial carrying value of the intangible asset acquired.

In October 2020, the Company amended and restated the agreement with One (the "2020 One Amendment") to cancel its obligation to issue to One the warrant for redeemable convertible preferred stock agreed to in the 2019 One Amendment . In return for cancelling the warrant, One received additional consideration consisting of a commercial milestone of €6.5 million (approximately $7.0 million at December 31, 2022) upon a weight loss product reaching €2.0 billion in cumulative net sales, and certain shareholders of One were granted warrants to purchase 522,009 shares of the Company's common stock. The warrant for redeemable convertible preferred stock was remeasured prior to settlement. Additionally, the Company granted One a contingent call option to buy back the 10% ownership that the Company acquired in the 2019 One Amendment at an exercise price of €6.0 million (approximately $6.4 million at December 31, 2022). The call option is only exercisable upon (1) a change of control or a deemed liquidation event by the Company,

as defined in the Company's Restated Certification of Incorporation or (2) the date in which the Company's current Chief Executive Officer is no longer affiliated with the Company in his capacity as either an executive officer or a member of the board of directors.

On August 9, 2022, the Company amended the exercise price of the One warrant holders' 1,353,062 previously issued common stock warrants from $4.26 to $1.45, in consideration for deferring payment of the remaining purchase price totaling €2.5 million (approximately $2.7 million at December 31, 2022) to acquire the 10% equity interest in One until March 31, 2023.

The Company recorded intangible asset amortization cost aggregated $2.3 million during each of the years ended December 31, 2022 and 2021. The Company recognized a loss attributable to the amendment to the Warrant Purchase Agreement of $0.3 million during the year ended December 31, 2022.

In connection with the acquisition of the 10% equity interest in One, the Company paid €2.5 million ($2.7 million) to One shareholders during the year ended December 31, 2022. The Company had remaining undiscounted payment obligations of €2.5 million and €5.0 million at December 31, 2022 and December 31, 2021, respectively ($2.7 million and $5.7 million at December 31, 2022 and December 31, 2021, respectively). The remaining payment obligation balance at December 31, 2022 and December 31, 2021 was recorded in accrued expenses in the accompanying consolidated balance sheet as it was expected to be settled within the next twelve months from the respective consolidated balance sheet dates. None of the future milestones under the amended and restated master agreement, have been met, or are deemed to be probable of being met, from inception of the One agreement, as amended and restated, through December 31, 2022.

The One S.r.l. call option was recorded as a liability held at fair value at the date of issuance and is remeasured at each subsequent reporting date with changes in fair value recorded in other income (expense) in the accompanying consolidated statements of operations. Fair value is determined using a Black-Scholes option pricing model. The significant inputs used in estimating the fair value of call option liability include the estimated fair value of the underlying stock price, expected term, risk free interest rate, and expected volatility.

The following represents a summary of the changes to the Company's One S.r.l. call option liability during the years ended December 31, 2022 and 2021, respectively (in thousands):

	Years Ended December 31,	
	2022	**2021**
Balance at Beginning of Period	$ 2,416	$ 1,545
Change in fair value	(1,462)	1,024
Foreign currency translation gain	(280)	(153)
Balance at the End of Period	$ 674	$ 2,416

The following weighted average assumptions were used to determine the fair value of the One S.r.l. call option liability at December 31, 2022 and December 31, 2021:

	December 31,	
	2022	**2021**
Expected term	4.0 years	2.0 years
Expected volatility	86.0%	62.0%
Expected dividend yield	0.0%	0.0%
Risk free interest rate	4.2%	0.70%
Estimated fair value of ownership interest	$ 1,772	$ 6,922
Exercise price of call option	$ 6,422	$ 6,806

Research Innovation Fund ("RIF") Financing

In August 2020, the Gelesis S.r.l. entered into a loan and equity agreement with RIF, an investment fund out of the EU, whereby Gelesis S.r.l. received €10.0 million (approximately $10.7 million at December 31, 2022) from RIF as an equity investment and €15.0 million (approximately $16.1 million at December 31, 2022) as a loan with a fixed interest rate of 6.35% per annum (see Note 12). The equity investment can be called by the Company, beginning in December 2023 and ending in December 2026, by paying the investment plus 15% percent annual interest. If the Company does not exercise this call option, beginning in January 2027 and ending in December 2027, RIF may put the investment to the Company at a cost of the investment amount plus 3.175% percent annual interest. The loan has a termination date of December 31, 2030 and is repayable over 8 years starting 24 months subsequent to its issuance. Any unpaid principal and interest must be repaid upon exercise of the call option by the Company, or subsequent exercise of a put option by RIF. At December 31, 2022, RIF holds approximately 20% of the equity of Gelesis S.r.l.

The Company concluded that Gelesis Inc. is the only equity investment at risk as RIF's investment is not considered equity due to the call and put options. The Company further evaluated the sufficiency of the equity at risk and concluded that given the fact that Gelesis S.r.l. had to receive the RIF investment, which represents subordinated financial support but not equity, the fair value of Gelesis Inc.

equity is not sufficient to absorb its expected losses resulting from its research and development operations and business plan, rather some of its expected losses will have to be absorbed by the RIF investment.

The RIF investment is equity held by a noncontrolling interest. Since the put option does not make the equity mandatorily redeemable, and the call option is held by the Company, the noncontrolling interest is not considered mandatorily redeemable and as such, is not presented as a liability. The noncontrolling interest is therefore classified as temporary equity – noncontrolling interest, and is accounted for in accordance with ASC 810, *Consolidation*.

The noncontrolling interest is initially recorded at €10.0 million (approximately $11.3 million at transaction date, net of issuance costs of $0.4 million), the consideration allocated to the shareholder investment based on its fair value. The Company has applied ASC 810 to subsequently remeasure the noncontrolling interest, which results in no losses being attributed to the noncontrolling interest, rather, only earnings of the Gelesis S.r.l. entity based on the shareholder rights as a whole instrument. However, the noncontrolling interest shall not be reduced below the current redemption value of the put option, which represents the initial investment plus the accrued rate of return of 3.175% per annum. Adjustments to the noncontrolling interest that result from accreting the put option to its redemption value are recorded to accumulated deficit in the accompanying consolidated balance sheets.

The Company recorded the following noncontrolling interest components in the consolidated statements of noncontrolling interest, redeemable convertible preferred stock and stockholders' deficit (in thousands):

	Years Ended December 31,	
	2022	2021
Balance at Beginning of Period	$ 11,855	$ 12,429
Accretion of put option	253	376
Income allocated to noncontrolling interest holder	1,095	—
Foreign currency translation adjustment	(613)	(950)
Balance at the End of Period	$ 12,590	$ 11,855

12. Debt

The Company's non-convertible debt outstanding at December 31, 2022 and December 31, 2021, respectively, is summarized as follows (in thousands):

	December 31,	
	2022	2021
Italian Economic Development Agency Loan	331	525
Intesa Sanpaolo Loan 1	7,094	8,507
Intesa Sanpaolo Loan 2	5,352	5,672
Horizon 2020 Loan	389	486
RIF Shareholders Loan	16,055	17,015
UniCredit Loan	4,421	5,630
Total debt obligation	$ 33,642	$ 37,835
Unamortized loan discount and issuance costs	(346)	(754)
Total debt obligation carrying amount	$ 33,296	$ 37,081
Current portion	$ 7,954	$ 1,950
Long-term portion	$ 25,342	$ 35,131

Italian Economic Development Agency Loan

In May 2014, the Company entered into a loan agreement with an Italian economic development agency in connection with a grant. In February 2016, the Company received a second transfer of financing under this loan agreement. Borrowings under the loan totaled €1.2 million (approximately $1.3 million at December 31, 2022), and the loan bears interest at 0.332% per annum The Company is required to make annual principal and interest payments from January 2017 through January 2024.

Intesa Sanpaolo Loan 1

In November 2019, the Company entered into a loan agreement with Intesa Sanpaolo. Initial borrowings under the loan totaled €2.4 million (approximately $2.6 million at December 31, 2022), net of transaction costs of €0.1 million (approximately $0.1 million at December 31, 2022), and the loan bears interest at base rate of 2.3% plus the 3-month Euribor rate per annum. The Company was required to make payments of interest only on borrowings under the loan agreement on a quarterly basis through and including October 31, 2021 (the interest only termination date), after which payments of principal in equal quarterly installments and accrued interest will be due until the loan matures on October 31, 2029. The Company pledged certain manufacturing facilities, excluding equipment, as collateral under this loan agreement.

During 2020, the Company borrowed an additional €5.0 million (approxfimately $5.4 million at December 31, 2022), net of transaction costs of less than €0.1 million. The additional borrowings under the loan had the same terms and repayment schedule as the November 2019 loan.

Intesa Sanpaolo Loan 2

In March 2021, the Company entered into another loan agreement with Intesa Sanpaolo for aggregate borrowings of up to €5.0 million. Borrowings under the second loan agreement upon closing and at December 31, 2022, totaled €4.8 million (approximately $5.1 million at December 31, 2022), net of transaction costs of €0.2 million (approximately $0.2 million at December 31, 2022), and the loan bears interest at a base rate of 2.75%. The Company is required to make payments of interest only on borrowings under the loan agreement on a monthly basis through March 2023 (the interest only termination date), after which payments of principal in equal monthly installments and accrued interest will be due until the loan matures on March 26, 2024.

Horizon 2020 Loan

In December 2019, as part of the Horizon 2020 Grant (see Note 11), the Company entered into a loan agreement with the Italian Finance Ministry. Borrowings under the loan totaled €0.3 million (approximately $0.3 million at December 31, 2022), net of transaction costs and discounts of less than €0.1 million, and the loan bears interest at 0.171% per annum. The Company is required to make payments of interest only on borrowings under the loan agreement on a semiannual basis through and including June 30, 2020 (the interest only termination date), after which payments of principal in equal semiannual installments and accrued interest will be due until the loan matures on June 30, 2028.

In October 2020, the Company borrowed an additional €0.2 million (approximately $0.2 million at December 31, 2022), net of transaction costs of less than €0.1 million. The additional borrowings under the loan had the same terms and repayment schedule as the December 2019 loan.

RIF Shareholders Loan

In August 2020, as part of the RIF financing transaction (see Note 11), the Company entered into a loan agreement with the shareholders of RIF. Borrowings under the loan totaled €14.5 million (approximately $15.5 million at December 31, 2022), net of transaction costs of €0.5 million (approximately $0.5 million at December 31, 2022), and the loan bears interest at 6.35% per annum. The Company is required to make payments of interest only on borrowings under the loan agreement on an annual basis starting December 31, 2020 and through and including December 30, 2022 (the interest only termination date), after which payments of principal in equal annual installments and accrued interest will be due until the loan matures on December 31, 2030. If either party exercises its call option or put option on the equity investment as part of the RIF Transaction, the unpaid principal and accrued interest as of that date must be paid by the Company.

UniCredit Loan

In November 2020, the Company entered into a loan agreement with UniCredit. Borrowings under the loan totaled €4.9 million (approximately $5.2 million at December 31, 2022), net of transaction costs and discounts of €0.1 million (approximately $0.1 million at December 31, 2022), and the loan bears interest at 2.12% per annum. The Company is required to make payments of principal and accrued interest on a semiannual basis starting December 10, 2021 until the loan matures on December 10, 2027.

2021 Bridge Financing

In December 2021, the Company issued convertible promissory notes to related parties in the principal amount of $27.0 million (see Note 20). At December 31, 2021, the outstanding balance under the 2021 convertible promissory notes was $27.1 million, recorded at fair value in the accompanying consolidated balance sheet. On January 19, 2022 the Company settled the convertible promissory notes in cash for principal plus accrued interest in the aggregate amount of $27.3 million. During the years ended December 31, 2022 and 2021, the Company recognized a fair value adjustment of $0.2 million and $0.1 million, respectively, relating to the 2021 convertible promissory notes on the accompanying consolidated statements of operations.

2022 Promissory Notes

In the third quarter of 2022, the Company issued three term promissory notes in the aggregate principal amount of $25.0 million to existing investor CMS, and existing investors and related parties PureTech Health LLC and SSD2 LLC, for an aggregate cash proceeds of $25.0 million. Each of the 2022 promissory notes is unsecured and bears interest at a rate of 15% per annum. Each promissory note matures on the earlier of (a) December 31, 2023 or (b) five (5) business days following a qualified financing. Upon a payment default under any promissory note that has not been cured after five days (i) the Company will be required to issue certain warrants to the holders as defined by the promissory note agreements and (ii) the holders will have the option to convert outstanding principal and accrued interest into a number of shares of Gelesis common stock as defined by the promissory note agreements.

At December 31, 2022, the aggregate outstanding balance of the 2022 promissory notes was $27.4 million recorded at fair value in the accompanying consolidated balance sheet. During the year ended December 31, 2022, the Company recognized a fair market adjustment of $2.4 million relating to the 2022 promissory notes.

The Company applied the provisions of ASC 815-15, *Embedded Derivatives,* elected to account for the 2022 promissory notes at fair value, and to not bifurcate the embedded derivative. The fair value of the promissory notes is determined using a multiple scenario-based valuation method. The fair value of the hybrid instrument was determined by calculating the value of the instrument in each scenario "with" the respective conversion feature and "without". The significant inputs used in estimating the fair value of the convertible promissory notes include the estimated discount rate, expected term, and the outcome probability with respect to each scenario.

The following assumptions were used to determine the fair value of the 2022 promissory notes at December 31, 2022:

Expected term	1 year
Weighted average discount rate	26.0%
Probability of repayment after qualified financing	50.0%
Probability of holder electing conversion option	50.0%

Interest Rate Swap Contract on Intesa Sanpaolo Loan 1

In November 2019, the Company entered into an interest rate swap ("IRS") contract with Intesa Sanpaolo S.p.A. concurrently with the execution of the Intesa Sanpaolo loan 1 agreement. The IRS contract covered the same period as the underlying Intesa Sanpaolo loan 1 and expires on October 31, 2029.

Fair value of the interest rate swap contract is determined based on quoted price in markets that are not active for which significant inputs are observable either directly or indirectly and thus represents a level 2 measurement.

The Company reported a fair value of $0.8 million for the IRS contract included other assets at December 31, 2022, and $0.1 million included in other long-term liabilities at December 31, 2021 in the accompanying consolidated balance sheets. Net gain attributable to the change in fair value of the IRS contract was $0.9 million for the year ended December 31, 2022. Net loss attributable to the change in fair value of the IRS contract was $0.1 million for the year ended December 31, 2021.

Future maturities with respect to non-convertible debt obligations outstanding at December 31, 2022 are as follows (in thousands):

	At December 31, 2022
2023	8,101
2024	5,445
2025	3,962
2026	3,983
2027	3,964
More than 5 years	8,186
Total maturities	$ 33,642

13. Warrant Liabilities

The following represents a summary of the warrant liabilities activity during the years ended December 31, 2022 and 2021 (in thousands):

	Legacy Gelesis Warrants	Private Placement Warrants	Total
Balance at December 31, 2020	$ 12,099	$ —	$ 12,099
Exercise of warrants	(3,924)	—	(3,924)
Change in fair value	7,646	—	7,646
Balance at December 31, 2021	$ 15,821	$ —	$ 15,821
Assumed upon Business Combination	—	8,140	8,140
Changes in fair value	926	(8,010)	(7,084)
Conversion and exchange upon Business Combination	(16,747)	—	(16,747)
Balance at December 31, 2022	$ —	$ 130	$ 130

Legacy Gelesis Redeemable Preferred Stock Warrants

The Legacy Gelesis warrants were evaluated under ASC 480 – *Distinguishing Liabilities from Equity* and it was determined that they met the requirements for separate accounting as freestanding financial instruments and should be classified as liabilities, as they relate to an obligation to issue shares that are potentially redeemable. The related liability is remeasured at each reporting date up to the exercise or expiration with increases or decreases in fair value being recorded in the consolidated statements of operations.

In connection with the Business Combination, Legacy Gelesis redeemable preferred stock warrants were reclassified from liability treatment to equity treatment pursuant to the terms of their exchange to New Gelesis warrants (see Note 15).

The following assumptions were used to determine the fair value of the warrant liability at December 31, 2021:

Expected term		0.1 years
Expected volatility		48.0%
Expected dividend yield		0.0%
Risk free interest rate		0.6%
Estimated fair value of the redeemable convertible preferred stock	$	22.36
Exercise price of warrants	$	0.04

Private Placement Warrants

At December 31, 2022, there were 7,520,000 Private Placement Warrants outstanding exercisable at $11.50 per share for common stock at the same terms as the Public Warrants. However, the warrants will not be redeemable by the Company for cash so long as they are held by the initial stockholders or their permitted transferees. The initial purchasers of the Private Placement Warrants, or their permitted transferees, also have the option to exercise the Private Placement Warrants on a cashless basis. If Private Placement Warrants are held by holders other than the initial purchasers thereof or their permitted transferees, the Private Placement Warrants will be redeemable by the Company and exercisable by the holders on the same basis as the Public Warrants.

The warrants were initially recorded at fair value with subsequent changes in fair value being recorded in the accompanying consolidated statements of operations. The warrants at issuance and at December 31, 2022, were valued utilizing a modified Monte Carlo Simulation value model and significant unobservable Level 3 inputs.

The following weighted-average assumptions were used to determine the fair value of the Private Placement Warrant liability at December 31, 2022:

		Private Placement Warrants
Expected term		4.0 years
Expected volatility		86.0%
Expected dividend yield		0.0%
Risk free interest rate		4.0%
Price of Gelesis Common Stock	$	0.29
Exercise price of warrants	$	11.50

14. Earnout Liability

The following represents a summary of the earnout liability activity during the year ended December 31, 2022 (in thousands):

		Earnout Liability
Balance at December 31, 2021	$	—
Recognized upon Business Combination		58,871
Changes in fair value		(58,308)
Balance at December 31, 2022	$	563

At Business Combination close and at December 31, 2022, there were 18,758,241 earnout shares underlying the liability, which were unissued and unvested. At December 31, 2022, none of the triggering events had been met.

The earnout liability was initially recorded at fair value with subsequent changes in fair value being recorded in the accompanying consolidated statements of operations. The earnout liability at issuance and at December 31, 2022, were valued utilizing a Monte Carlo Simulation and significant unobservable Level 3 inputs.

The following weighted-average assumptions were used to determine the fair value of the earnout liability at December 31, 2022:

		Earnout Liability
Expected term		4.0 years
Expected volatility		86.0%
Expected dividend yield		0.0%
Risk free interest rate		4.0%
Price of Gelesis Common Stock	$	0.29

15. Stockholders' Equity (Deficit)

Common Stock

The Company's authorized capital stock consists of (a) 900,000,000 shares of common stock, par value $0.0001 per share; and (b) 250,000,000 shares of preferred stock, par value $0.0001 per share. At December 31, 2022, there were 73,325,022 shares of common stock issued and outstanding.

Common Stock Purchase Agreement

On August 11, 2022, the Company entered into a Common Stock Purchase Agreement and a Registration Rights Agreement (the "Purchase Agreement") with B. Riley Principal Capital II, LLC ("B. Riley"). Pursuant to the agreement, the Company will have the right, but not the obligation, to sell to B. Riley up to the lesser of (i) $50,000,000 of newly issued shares of common stock, and (ii) 14,506,475 shares of common stock (which is the number of shares equal to approximately 19.99% of the aggregate number of shares of the Company's common stock issued and outstanding immediately prior to the execution of the agreement) at 97% of the volume weighted average price ("VWAP") of the Company's common stock calculated in accordance with the Purchase Agreement, from time to time during the 24-month term commencing from the effectiveness date of the corresponding Form S-1 registration statement on September 6th, 2022. Sales and timing of any sales of Class A common stock are solely at the election of the Company, and the Company is under no obligation to sell any securities to B. Riley under the Purchase Agreement. As consideration for B. Riley's commitment to purchase shares of the Company's common stock, the Company issued 355,361 shares of its common stock as commitment shares. The Company incurred an aggregate cost of approximately $1.2 million in connection with the Purchase Agreement, including $0.5 million for the fair value of the 355,361 commitment shares issued to B. Riley.

The Company recorded $1.2 million legal and professional costs in the accompanying consolidated statement of operations during the year ended December 31, 2022, and recorded $0.5 million of additional paid-in capital in the accompanying consolidated balance sheets as of December 31, 2022 with respect to the fair value of the 355,361 common stock commitment shares issued to B. Riley.

The Company issued a total of 34,246 shares of its common stock and raised less than $0.1 million gross proceeds under the Purchase Agreement for the year ended December 31, 2022.

Legacy Redeemable Convertible Preferred Stock

At December 31, 2021 and immediately prior to the Business Combination, Legacy Gelesis had outstanding redeemable convertible preferred stock which are collectively referred to as "redeemable convertible preferred stock." Immediately prior to the closing of the Business Combination, Legacy Gelesis redeemable convertible preferred stock converted into Legacy Gelesis common stock and was subsequently split according to the exchange ratio of 2.59. Upon closing of the Business Combination, holders received shares of common stock of the Company on a one-to-one basis.

Public Warrants

In connection with the Business Combination the Company assumed 13,800,000 Public Warrants, which entitle the holder to acquire common stock, which are exercisable at an exercise price of $11.50 per share. The Public Warrants will expire at on the earlier to occur of five years after the completion of the Business Combination or redemption.

Once the Public Warrants become exercisable, the Company may call the Public Warrants for redemption for cash:

- in whole and not in part;
- at a price of $0.01 per warrant;
- upon not less than thirty (30) days' prior written notice of redemption (the "30-day redemption period") to each warrant holder; and
- if, and only if, the closing price of the Common Stock equals or exceeds $18.00 per share (as adjusted for stock splits, stock capitalizations, reorganizations, recapitalizations and the like) for any twenty(20) trading days within a thirty (30)-trading day period ending three (3) business days before the Company sends the notice of redemption to the warrant holders.

If the Company calls the Public Warrants for redemption, the Company will have the option to require all holders that wish to exercise the Public Warrants to do so on a cashless basis, as described in the warrant agreement. Additionally, in no event will the Company be required to net cash settle.

At December 31, 2022, there were 13,800,000 Public Warrants outstanding.

Rollover Warrants

Immediately prior to the closing of the Business Combination, Legacy Gelesis redeemable preferred stock warrants were converted into Legacy Gelesis common warrants and were subsequently split according to the exchange ratio of 2.59. Upon closing of the

Business Combination, holders received rollover common stock warrants of the Company on a one-to-one basis. At close of the Business Combination and December 31, 2022, there were 1,836,429 and 1,660,303 rollover warrants outstanding, respectively, with an exercise price of $0.02. During the year ended December 31, 2022, 176,126 rollover warrants were exercised for proceeds of less than $0.1 million.

Immediately prior to the closing of the Business Combination, existing Legacy Gelesis common warrants were also split according to the exchange ratio of 2.59. Upon closing of the Business Combination, holders received warrants to purchase shares of common stock of the Company on a one-to-one basis. At close of the Business Combination and at December 31, 2022, respectively, there were 1,353,062 of these warrants outstanding with an exercise price of $4.26.

The Company's common stock reserved for future issuances are summarized as follows:

	December 31,	
	2022	2021
Common stock issued upon option exercise and RSUs vesting	16,881,549	13,486,708
Conversion of all classes of redeemable convertible preferred stock	—	48,566,655
Issuances upon exercise of Legacy Gelesis warrants	—	1,836,429
Issuances upon exercise of common stock warrants	24,733,365	1,353,062
Earnout shares	23,482,845	—
Total common stock reserved for future issuance	65,097,759	65,242,854

16. Stock-Based Compensation

2021 Stock Option Plan

In January 2022, the Company's Board of Directors approved the 2021 Stock Option and Incentive Plan (the "2021 Plan"), which supersedes the 2016 Stock Option and Grant Plan and the 2006 Stock Incentive Plan and provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards and restricted stock units to employees, directors, and nonemployees of the Company. The 2021 Plan was authorized initially to issue 9,583,570 shares, plus on January 1, 2023 and each January 1 thereafter, the number of shares of Common Stock reserved and available for issuance under the Plan shall be cumulatively increased by 4 percent of the number of shares of Common Stock issued and outstanding on the immediately preceding December 31. Under the 2021 Plan, 3,977,252 shares remained available for issuance at December 31, 2022.

Options and restricted stock awards generally vest based on the grantee's continued service with the Company during a specified period following a grant as determined by the Board of Directors and expire ten years from the grant date. In general, awards typically vest in three to four years, but vesting conditions can vary based on the discretion of the Company's Board of Directors.

The fair value of the options is estimated at the grant date using Black-Scholes and recognized over the vesting period, taking into account the terms and conditions upon which options are granted. The fair value of restricted stock awards is the fair value at the date of grant reduced by the exercise price of the award, if any. The fair value of both options and restricted stock awards are amortized on a straight-line basis over the requisite service period of the awards.

Stock-based compensation expense is summarized for employees and nonemployees, by category in the accompanying consolidated statements of operations as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Research and development	$ 9,698	$ 1,565
Selling, general and administrative	20,079	3,967
Total	$ 29,777	$ 5,532

Stock Option Activity

The following table summarizes the Company's stock option activity during the year ended December 31, 2022:

	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	4,889,820	$ 10.39	6.17	$ 54,449
Retroactive application of reverse recapitalization	7,784,666	(6.38)		
Adjusted and Outstanding at December 31, 2021	12,674,486	$ 4.01	6.17	$ 54,449
Granted	2,658,185	$ 3.35		
Exercised	(207,033)	$ 0.58		
Forfeited - unvested	(972,349)	$ 4.64		
Forfeited - vested	(63,718)	$ 4.31		
Expired	(1,291,092)	$ 3.13		
Outstanding at December 31, 2022	12,798,479	$ 3.97	5.80	$ 25
Exercisable at December 31, 2022	9,664,164	$ 3.92	4.84	$ 25
Vested and Expected to Vest at December 31, 2022	12,798,479	$ 3.97	5.80	$ 25

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the common stock. The total fair value of options vested during the year ended December 31, 2022 was $4.8 million.

The fair value of each option issued was estimated at the date of grant using Black-Scholes with the following weighted-average assumptions:

	Years Ended December 31,	
	2022	2021
Market price of common stock	$ 3.35	$ 20.02
Expected volatility	72.4%	60.1%
Expected term (in years)	6.1	5.8
Risk-free interest rate	1.7%	1.1%
Expected dividend yield	0.0%	0.0%

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2022 and 2021 were $2.17 and $11.25 per share, respectively. At December 31, 2022 and December 31, 2021, there was $6.6 million and $8.7 million, respectively, of unrecognized compensation cost related to unvested stock option grants under the 2021 Plan, which was expected to be recognized over a weighted-average period of 2.1 and 1.7 years, respectively.

Restricted Stock Unit ("RSU") Activity

During the year ended December 31, 2022, the Company issued 4,555,197 RSUs at a weighted-average fair value of $3.46 per unit.

The following table summarizes the Company's RSU activity during the year ended December 31, 2022:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Outstanding and Unvested at December 31, 2021	313,354	$ 21.41
Retroactive application of reverse recapitalization	498,868	$ (13.15)
Adjusted and Outstanding and Unvested at December 31, 2021	812,222	$ 8.26
Granted	4,555,197	$ 3.46
Vested	(337,969)	$ 4.81
Forfeited	(946,380)	$ 3.44
Outstanding and Unvested at December 31, 2022	4,083,070	$ 4.31

Each RSU entitles the holder to one share of common stock on vesting and the RSU awards are based on a cliff vesting schedule over requisite service periods in which the Company recognizes compensation expense for the RSUs. Vesting of the RSUs is subject to the satisfaction of certain service and or certain performance conditions. The Company recognizes the estimated grant date fair value of these awards as stock-based compensation expense over the service and/or performance periods based upon its determination of whether it is probable that the service and or performance conditions will be achieved. The Company assesses the probability of achieving the service and or performance conditions at each reporting period. Cumulative adjustments, if any, are recorded to reflect subsequent changes in the estimated or actual outcome of service and or performance-related conditions.

At December 31, 2022 and December 31, 2021, unrecognized compensation cost for RSU awards granted totaled $7.9 million and $6.7 million, respectively, which was expected to be recognized over a weighted-average period of 3.1 and 0.9 years, respectively.

17. Income Taxes

Consolidated (loss) income before income taxes on a geographic basis during the years ended December 31, 2022 and 2021 are as follows (in thousands):

	Years Ended December 31,	
	2022	2021
United States	$ (63,850)	$ (86,693)
Non-U.S.	8,550	(6,637)
Total	$ (55,300)	$ (93,330)

The provision for income taxes consists of the following components during the years ended December 31, 2022 and 2021 (in thousands):

	Years Ended December 31,	
	2022	2021
Current tax expense:		
U.S. federal	$ —	$ —
Foreign	480	17
Total current tax expense	480	17
Deferred tax expense:		
U.S. federal	—	—
State	—	—
Foreign	—	—
Total deferred tax expense	—	—
Total provision for income taxes	$ 480	$ 17

A reconciliation setting forth the differences between the effective tax rates of the Company for the years ended December 31, 2022 and 2021 and the U.S. federal statutory tax rate is as follows:

	Years Ended December 31,	
	2022	2021
U.S. Federal income tax provision expense at statutory rate	21.0%	21.0%
Effect of nondeductible stock-based compensation	(0.8)%	0.8%
Foreign rate differential	(1.2)%	0.2%
Mark to market of warrant liabilities	24.0%	(1.7)%
State taxes net of federal benefit	10.7%	4.3%
Non-deductible financing expenses	0.4%	(0.3)%
Valuation allowance	(53.6)%	(24.2)%
Investment transfer	—	—
Other differences	0.9%	(0.4)%
US federal and state research credits	0.6%	0.4%
Uncertain tax positions	(0.1)%	(0.1)%
Foreign earnings includible in US	—	—
Transaction Costs	(0.9)%	—
GILTI	(1.9)%	—
Effective income tax rate	(0.9)%	0.0%

Significant components of the Company's consolidated deferred tax assets and liabilities at December 31, 2022 and 2021 are as follows at (in thousands):

	At December 31,	
	2022	2021
Deferred tax assets:		
Federal net operating loss carryforwards	$ 54,005	$ 40,469
State net operating loss carryforwards	13,705	10,643
Equity compensation	12,331	5,620
Accruals and reserves	16	-
Uncollected grants	993	998
Investment in subsidiaries	3,766	3,820
Research credits	1,823	1,578
Other assets	1,549	152
Deferred income	—	239
Interest	—	257
Lease liabilities	411	547
Inventory reserve	3,430	—
Section 174 adjustment	3,572	—
Total deferred tax assets	95,601	64,323
Valuation allowance	(91,842)	(59,841)
Total deferred tax assets net of valuation allowance	3,759	4,482
Deferred tax liabilities:		
Intangible assets and amortization	(3,332)	(3,932)
Right-of-use asset	(400)	(536)
Other liabilities	(27)	(14)
Total deferred tax liabilities	(3,759)	(4,482)
Net deferred tax assets	$ —	$ —

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amount used for income tax purposes. At December 31, 2022 and 2021, the Company has federal net operating loss carryforwards totaling $254.7 million and $184.6 million, respectively, of which $63.5 million expire in 2027 through 2037 and $191.2 million do not expire as of December 31, 2022. At December 31, 2022 and 2021, the Company has state net operating loss carryforwards totaling $221.2 million and $168.4 million, respectively, which expire in 2030 through 2041, as well as other temporary differences and attributes that will be available to offset regular taxable income during the carryforward period. At December 31, 2022, the Company has foreign net operating loss carryforwards of $2.2 million which do not expire.

The Company files income tax returns in Italy, the United States and in various state jurisdictions with varying statutes of limitations. Due to net operating losses incurred, the Company's tax returns from inception to date are subject to examination by taxing authorities.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its net deferred tax assets and determined that it is not more likely than not that the Company will recognize the benefits of the net deferred tax assets. Therefore, a full valuation allowance has been recorded against the balance of net deferred tax assets in the United States. Additionally, the Company has determined that it is not more likely than not that the Company will recognize the benefits of the net deferred tax assets in Italy, primarily due to uncertainty regarding continued funding of the operations of Italy and from the restructuring of the intercompany services agreement between Gelesis, Inc., and Gelesis S.r.l., in connection with the RIF financing (see Note 11). As a result, the Company maintained a full valuation allowance against the balance of net deferred tax assets in Italy as of December 31, 2022 and December 31, 2021, respectively. The Company will continue to evaluate all positive and negative evidence each period.

The change in the valuation allowance during the years ended December 31, 2022 and 2021 was an increase of $32.2 million and $22.4 million, respectively. The increase in the valuation allowance during the years ended December 31, 2022 and December 31, 2021, respectively, was primarily due to the increase in net operating losses generated by the U.S. and foreign operations, net.

The Company generally considers all earnings generated in Italy to be indefinitely reinvested. Therefore, the Company does not accrue U.S. taxes on the repatriation of the foreign earnings it considers to be indefinitely reinvested outside of the U.S. At December 31, 2022, the Company had not provided for federal income tax on $0.8 million of accumulated undistributed deficit of its foreign subsidiaries. In the event the Company were to repatriate the foreign earnings, the Company does not estimate the repatriation being subject to taxation.

The Company follows the provisions of ASC 740-10, Accounting for Uncertainty in Income Taxes, which specifies how tax benefits for uncertain tax positions are to be recognized, measured, and recorded in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim period guidance, among other provisions. At December 31, 2022 and 2021, the Company has not recorded any liability for uncertain tax positions which relate primarily to certain federal and state research tax credits. The Company presents the uncertain tax positions as a reduction to the gross deferred tax assets with respect to research credits. The Company's policy is to recognize interest and penalties accrued on any uncertain tax positions as a component of income tax expense, if any, in its consolidated statements of operations. For the years ended December 31, 2022 and 2021, no estimated interest or penalties were recognized on uncertain tax positions. The Company does not expect that the amounts of uncertain tax positions will change significantly within the next twelve months. A reconciliation of the beginning and ending amount of uncertain tax positions is as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Unrecognized tax benefits at the beginning of year	$ (352)	$ (281)
Increase for current year positions	(65)	(71)
Increase for prior year positions	—	—
Expiration of statute of limitations	—	—
Unrecognized tax benefits at the end of year	(417)	(352)
Gross research credit tax assets	2,240	1,930
Net research credit tax assets	$ 1,823	$ 1,578

18. Earnings (Loss) per Share

The weighted-average common shares outstanding and thus the net loss per share calculations and potentially dilutive security amounts for all periods prior to the Business Combination have been retrospectively adjusted to the equivalent number of shares outstanding immediately after the Business Combination to effect the reverse recapitalization. Historically reported weighted average shares outstanding have been multiplied by the exchange ratio of approximately 2.59. See Note 3 for further information.

Basic and diluted loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	Years Ended December 31,	
	2022	2021
Numerator:		
Net loss	$ (55,780)	$ (93,347)
Accretion of redeemable convertible preferred stock to redemption value	(37,934)	(94,134)
Accretion of noncontrolling interest put option to redemption value	(253)	(376)
Income allocated to noncontrolling interest holder	(1,095)	—
Net loss attributable to common stockholders	$ (95,062)	$ (187,857)
Denominator:		
Weighted average common shares outstanding, basic and diluted	70,300,772	5,712,042
Net loss per share, basic and diluted	$ (1.35)	$ (32.89)

The Company's potential dilutive securities, which include stock options, RSUs, warrants and earnout shares have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same for all periods presented. The Company excluded the following potential common stock, presented based on amounts outstanding at December 31, 2022 and 2021 from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect.

	December 31,	
	2022	2021
Convertible preferred stock	—	48,566,655
Warrants on convertible preferred stock	—	1,836,429
Options and RSUs to acquire common stock	16,881,549	13,555,474
Warrants on common stock	24,733,365	1,353,062
Earnout shares	—	—
Total	41,614,914	65,311,620

Total potentially dilutive common share equivalents for the year ended December 31, 2022, excludes 23,482,845 shares related to the earnout liability as these shares are contingently issuable upon meeting certain triggering events.

19. Commitments and Contingencies

Operating Leases

In June 2019, the Company entered into an operating lease agreement with PureTech Health LLC, or PureTech, for office space located in Boston, Massachusetts. The lease expires in August 2025, with total lease payments of $3.2 million over the term. The remaining noncancelable term of the Company's operating leases was 2.6 years at December 31, 2022, and the weighted average discount rate was 5.3%.

The following table summarizes the Company's operating lease activity (in thousands):

	Years Ended December 31,	
	2022	2021
Lease liabilities, current	597	541
Lease liabilities, net of current portion	967	1,519
Total operating lease liabilities	$ 1,564	2,060
Operating lease rental expense	$ 656	$ 434

Future maturities of the lease liability under the Company's noncancelable operating leases at December 31, 2022 are as follows (in thousands):

	At December 31, 2022
2023	669
2024	579
2025	388
2026	34
2027	16
More than 5 years	-
Total undiscounted lease maturities	$ 1,686
Imputed interest	(122)
Total lease liability	$ 1,564

Royalty Agreements

Expenses from royalty agreements on net product sales and sublicense income is recognized as a cost of goods sold in the accompanying consolidated statements of operations during the period in which the associated revenues are recognized.

PureTech

In December 2009, the Company entered into a royalty and sublicense income agreement with PureTech, a significant stockholder in the Company, whereby the Company is required to pay PureTech a 2.0% royalty on net product sales received as a result of developing products and technology using the intellectual property purchased from One.

One S.r.l

Under the amended and restated master agreement with One, the Company is required to pay a 2.0% royalty on net product sales and an aggregate of €17.5 million (approximately $18.7 million at December 31, 2022) upon the achievement of certain commercial milestones of new medical indications as well as Plenity and pay royalties on net product sales and/or a percentage of sublicense income. At December 31, 2022, none of the milestones have been met.

Grant Agreements

The Company has been awarded grants from governmental agencies, which are recognized as income as the qualifying expenses are incurred (see Note 11). The grant agreements contain certain provisions, including, among others, maintaining a physical presence in the region for defined periods. Failure to comply with these covenants would require either a full or partial refund of the grant to the granting authority.

Research and Development Tax Credits

The Company's subsidiary, Gelesis S.r.l., which conducts core manufacturing and research and development activities on behalf of the Company, is eligible to receive a non-income based and non-refundable tax credits for qualified research and development activities. The Company has earned research and development tax credits in Italy for qualifying expenses incurred by performing certain research and development activities.

In December 2018, the Italian government passed a new budget law, effective January 1, 2019, that amended the eligibility criteria for recognizing qualifying research and development tax credits ("2019 Budget Law"). The 2019 Budget Law requires retroactive application for research and development tax credits earned during the year ended December 31, 2019. Under the 2019 Budget Law, research and development tax credits claimed in prior periods under previous interpretations of the research and development tax credit law may potentially be repaid by the Company.

The Company evaluated the potential loss under ASC 450, *Contingencies*. The Company concluded that the likelihood of a potential loss arising from this matter is probable.

The Company has recorded $0.0 million and $3.0 million as a component of other long-term liabilities in the accompanying consolidated balance sheets at December 31, 2022 and December 31, 2021, respectively. In October 2021, the Italian federal tax authority initiated an audit of the research and development tax credits for the calendar years 2017 through 2019. The Company concluded the audit with the Italian tax authorities by the end of 2022 which did not result in any material impact on the accompanying consolidated statement of operations.

Litigation

In connection with the Business Combination, the Company received a litigation demand letter from certain purported stockholders alleging that the Company was required to provide holders of Class A Common Stock a separate class vote in connection with proposed amendments of the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares, such that separate votes can be cast on the proposed increase in the number of shares of Class A common stock and the proposed increase in the number of shares of preferred stock. During the year ended December 31, 2022, the Company reached an agreement to resolve the claim and settled for an immaterial cash payment.

20. Related Party Transactions

The Company had the following transactions with related parties:

PureTech

In June 2019, PureTech executed a sublease agreement with the Company (see Note 19). With respect to the sublease, the Company incurred lease expense of $0.5 million and $0.5 million during the years ended December 31, 2022 and 2021, respectively, recorded in general and administrative expenses in the accompanying consolidated statements of operations. The Company incurred royalty expense of $0.5 million and $0.2 million in connection with the PureTech royalty agreement (see Note 19) during the years ended December 31, 2022 and 2021, respectively, recorded in cost of goods sold in the accompanying consolidated statements of operations. The Company had an accounts payable balance to PureTech of $0.1 million and $0.1 million at December 31, 2022 and December 31, 2021, respectively, in the accompanying consolidated balance sheets.

On December 13, 2021, the Company issued a convertible promissory note to PureTech in the principal amount of $15.0 million (see Note 12). At December 31, 2021, the outstanding balance was $15.1 million, recorded at fair value in the accompanying consolidated balance sheets. On January 19, 2022 the Company settled the convertible promissory notes in cash for principal plus accrued interest in the aggregate amount of $15.2 million. During the years ended December 31, 2022 and 2021, the Company recognized a loss of $0.1 million with respect to the change in fair value of the PureTech 2021 convertible promissory notes on the accompanying consolidated statements of operations.

On July 25, 2022, the Company issued a promissory note to PureTech in the principal amount of $15.0 million (see Note 12). At December 31, 2022, the outstanding balance of the promissory note was $16.6 million recorded at fair value in the accompanying consolidated balance sheets. During the year ended December 31, 2022, the Company recognized a loss of $1.6 million with respect to the change in the fair value of the promissory notes.

SSD2

On December 13, 2021, the Company issued a convertible promissory note to SSD2 in the principal amount of $12.0 million (see Note 12). At December 31, 2021, the outstanding balance was $12.1 million, recorded at fair value in the accompanying consolidated balance sheets. On January 19, 2022 the Company settled the convertible promissory notes in cash for principal plus accrued interest in the aggregate amount of $12.1 million. During the years ended December 31, 2022 and 2021, the Company recognized a loss of $0.1 million and less than $0.1 million, respectively, with respect to the change in fair value of the SSD2 2021 convertible promissory notes on the accompanying consolidated statements of operations.

On July 25, 2022, the Company issued a promissory note to SSD2 in the principal amount of $5.0 million (see Note 12). At December 31, 2022, the outstanding balance of the promissory note was $5.5 million recorded at fair value in the accompanying consolidated balance sheets. During the year ended December 31, 2022, the Company recognized a loss of $0.5 million with respect to the change in the fair value of the promissory notes.

One S.r.l

Consulting Agreement with Founder of One

The Company and one of the founders of One, who is also a stockholder of the Company, entered into a consulting agreement for the development of the Company's science and technology. The Company incurred costs for consulting services received from the founder of One totaling $0.2 million and $0.3 million during the years ended December 31, 2022 and 2021, respectively, recorded in research and development expense in the accompanying consolidated statements of operations. The Company recorded an accounts payable balance to the founder of less than $0.1 million at both December 31, 2022 and December 31, 2021, respectively, in the accompanying consolidated balance sheets.

Acquisition of One

In connection with the amended and restated master agreement with One (see Note 11), the Company acquired a 10.0% equity interest in One in exchange for cash consideration. During the year ended December 31, 2022 the Company made a payment of $2.9 million to One shareholders with respect to the acquisition. The Company had remaining undiscounted payments of €2.5 million and €5.0 million due to One at December 31, 2022 and December 31, 2021, respectively (approximately $2.7 million and $5.7 million due to One at December 31, 2022 and December 31, 2021, respectively). The balance at December 31, 2021 and December 31, 2022 was recorded in accrued expenses in the accompanying consolidated balance sheets as it is expected to be settled within the next twelve months.

Additionally, the Company incurred royalty expense of $0.5 million and $0.2 million with One (see Note 19) during the years ended December 31, 2022 and 2021, respectively, recorded in cost of goods sold in the accompanying consolidated statements of operations. The Company had an accrued expense balance of $2.7 million and $6.7 million at December 31, 2022 and December 31, 2021, respectively, relating to the One acquisition payment obligations and accrued royalties in the accompanying consolidated balance sheets.

RIF Transaction

In connection with the RIF transaction entered into in August 2020, the Company received $12.3 million from RIF as an equity investment that can be called by the Company beginning in December 2023 and ending in December 2026 by paying the investment plus 15.0% percent annual interest or put by RIF starting in January 2027 and ending in December 2027 for the investment amount plus 3.175% percent annual interest. RIF holds approximately 20% of the equity of Gelesis S.r.l. at December 31, 2022 (see Note 11). In addition, the shareholders of RIF provided the Company with a loan of €14.5 million ($15.5 million at December 31, 2022) with a fixed interest rate of 6.35% per annum (see Note 12).

21. Employee Benefit Plan

The Company has a 401(k) retirement plan in which substantially all U.S. employees are eligible to participate. Eligible employees may elect to contribute up to the maximum limits, as set by the Internal Revenue Service, of their eligible compensation. The Company made discretionary plan contributions of $0.2 million and $0.2 million during the years ended December 31, 2022 and 2021, respectively.

22. Subsequent Events

The Company has evaluated subsequent events which may require adjustment to or disclosure in the consolidated financial statements through the date of issuance of these consolidated financial statements.

In November 2022, the Company received letters from the NYSE indicating that the Company was not in compliance with its continued listing standards of (1) average closing price of a security of not less than $1.00 over a consecutive 30 trading-day period and (2) average market capitalization of not less than $50 million over a 30 trading-day period and stockholders' equity of not less than $50 million. The Company is closely monitoring the closing share price of its common stock and intends to regain compliance. The Company has had correspondence with the NYSE regarding this matter, and its business plan to comply with the NYSE listing standards was accepted by the NYSE in February 2023. If the Company is unable to satisfy the NYSE listing requirements by their respective deadlines, the Company will be subject to the NYSE's suspension and delisting procedures.

Effective January 20, 2023, the Company's Public Warrants, which were previously listed under the symbol "GLS WS", were delisted from the NYSE due to "abnormally low" price levels.

On February 21, 2023, the Company entered into a Note and Warrant Purchase Agreement with PureTech, pursuant to which the Company issued a short term convertible senior secured note in the aggregate principal amount of $5.0 million and warrants to purchase 23,688,047 shares of Common Stock. The warrants have an exercise price of $0.2744 and may not be exercised prior to the receipt of stockholder approval. The short term convertible senior secured note bears interest at a rate of 12% per annum, and matures on July 31, 2023, unless earlier converted or the maturity is extended as described within the definitive agreements. The Company may issue an additional $5.0 million to PureTech upon mutual acceptance of the Company meeting certain conditions.

On March 18, 2023, NYSE notified the Company that they had considered the closing price of $0.11 of the Company's Common Stock on March 17, 2023 to be close to an "abnormally low selling price" and that continued trading at such low price could result in immediate delisting of the Company's Common Stock. On March 18, 2023, NYSE also indicated that there is a potential for the Company to fall below the $15 million 30-trading-day average market capitalization standard which could result in immediate delisting of the Company's Common Stock.

Exhibit 10.4

GELESIS, INC.

2006 STOCK INCENTIVE PLAN

1.Purpose

The purpose of this 2006 Stock Incentive Plan (the "Plan") of Gelesis, Inc., a Delaware corporation (the "Company"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing such persons with equity ownership opportunities and performance-based incentives and thereby better aligning the interests of such persons with those of the Company's stockholders. Except where the context otherwise requires, the term "Company" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "Board").

2.Eligibility

All of the Company's employees, officers, directors, consultants and advisors are eligible to be granted options, restricted stock awards, or other stock-based awards (each, an "Award") under the Plan. Each person who has been granted an Award under the Plan shall be deemed a "Participant".

3.Administration and Delegation

(a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient to carry the Plan into effect and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award. No director or person acting pursuant to the authority delegated by the Board shall be liable for any action or determination relating to or under the Plan made in good faith.

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "Committee"). All references in the Plan to the "Board" shall mean the Board or a Committee of the Board or the executive officers referred to in Section 3(c) to the extent that the Board's powers or authority under the Plan have been delegated to such Committee or executive officers.

(c) Delegation to Executive Officers. To the extent permitted by applicable law, the Board may delegate to one or more executive officers of the Company the power to grant Awards to employees or officers of the Company or any of its present or future subsidiary corporations and to exercise such other powers under the Plan as the Board may determine, provided that the Board shall fix the terms of the Awards to be granted by such executive officers (including the exercise price of such Awards, which may include a formula by which the exercise price will be determined) and the maximum number of shares subject to Awards that the executive officers may grant; provided further, however, that no executive officer shall be authorized to grant Awards to any "executive officer" of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) or to any "officer" of the Company (as defined by Rule 16a-1 under the Exchange Act).

4. Stock Available for Awards.

Subject to adjustment under Section 8, Awards may be made under the Plan for up to 1,500,000 shares of common stock, $.0001 par value per share, of the Company (the "Common Stock"). If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan, subject, however, in the case of Incentive Stock Options (as hereinafter defined), to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares. At no time while there is any Option (as defined below) outstanding and held by a Participant who was a resident of the State of California on the date of grant of such Option, shall the total number of shares of Common Stock issuable upon exercise of all outstanding options and the total number of shares provided for under any stock bonus or similar plan of the Company exceed the applicable percentage as calculated in accordance with the conditions and exclusions of Section 260.140.45 of the California Code of Regulations, based on the shares of the Company which are outstanding at the time the calculation is made (the "California Regulations").

5. Stock Options

(a) General. The Board may grant options to purchase Common Stock (each, an "Option") and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable. An Option which is not intended to be an Incentive Stock Option (as hereinafter defined) shall be designated a "Nonstatutory Stock Option".

(b) Incentive Stock Options. An Option that the Board intends to be an "incentive stock option" as defined in Section 422 of the Code (an "Incentive Stock Option") shall only be granted to employees of the Company and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. The Company shall have no

liability to a Participant, or any other party, if an Option (or any part thereof) that is intended to be an Incentive Stock Option is not an Incentive Stock Option.

(c) Exercise Price. The Board shall establish the exercise price at the time each Option is granted and specify it in the applicable option agreement.

(d) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement.

(e) Exercise of Option. Options may be exercised by delivery to the Company of a written notice of exercise signed by the proper person or by any other form of notice (including electronic notice) approved by the Board together with payment in full as specified in Section 5(f) for the number of shares for which the Option is exercised.

(f) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as the Board may, in its sole discretion, otherwise provide in an option agreement, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) when the Common Stock is registered under the Securities Exchange Act of 1934 (the "Exchange Act"), by delivery of shares of Common Stock owned by the Participant valued at their fair market value as determined by (or in a manner approved by) the Board in good faith ("Fair Market Value"), provided (i) such method of payment is then permitted under applicable law and (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant at least six months prior to such delivery;

(4) to the extent permitted by applicable law and by the Board, in its sole discretion by (i) delivery of a promissory note of the Participant to the Company on terms determined by the Board, or (ii) payment of such other lawful consideration as the Board may determine; or

(5) by any combination of the above permitted forms of payment.

(g) Substitute Options. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Options in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute Options may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Options contained in the other sections of this Section 5 or in Section 2.

6.Restricted Stock

(a) Grants. The Board may grant Awards entitling recipients to acquire shares of Common Stock, subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award (each, a "Restricted Stock Award").

(b) Terms and Conditions. The Board shall determine the terms and conditions of any such Restricted Stock Award, including the conditions for repurchase (or forfeiture) and the issue price, if any.

(c) Stock Certificates. Any stock certificates issued in respect of a Restricted Stock Award shall be registered in the name of the Participant and, unless otherwise determined by the Board, deposited by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death (the "Designated Beneficiary"). In the absence of an effective designation by a Participant, Designated Beneficiary shall mean the Participant's estate.

7.Other Stock-Based Awards

The Board shall have the right to grant other Awards based upon the Common Stock having such terms and conditions as the Board may determine, including the grant of shares based upon certain conditions, the grant of securities convertible into Common Stock and the grant of stock appreciation rights.

8.Adjustments for Changes in Common Stock and Certain Other Events

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under this Plan, (ii) the number and class of securities and exercise price per share subject to each outstanding Option, (iii) the repurchase price per share subject to each outstanding Restricted Stock Award, and (iv) the terms of each other outstanding Award shall be appropriately adjusted by the Company (or substituted Awards may be made, if applicable) to the extent the Board shall determine, in good faith, that such an adjustment (or substitution) is necessary and appropriate. If this Section 8(a) applies and Section 8(c) also applies to any event, Section 8(c) shall be applicable to such event, and this Section 8(a) shall not be applicable.

(b) Liquidation or Dissolution. In the event of a proposed liquidation or dissolution of the Company, the Board shall upon written notice to the Participants provide that all then unexercised Options will (i) become exercisable in full as of a specified time at least 10 business days prior to the effective date of such liquidation or dissolution and (ii) terminate effective upon

such liquidation or dissolution, except to the extent exercised before such effective date. The Board may specify the effect of a liquidation or dissolution on any Restricted Stock Award or other Award granted under the Plan at the time of the grant of such Award.

(c) Reorganization Events

(1) Definition. A "Reorganization Event" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or (b) any exchange of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange transaction.

(2) Consequences of a Reorganization Event on Options. Upon the occurrence of a Reorganization Event, or the execution by the Company of any agreement with respect to a Reorganization Event, the Board shall provide that all outstanding Options shall be assumed, or equivalent options shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof). For purposes hereof, an Option shall be considered to be assumed if, following consummation of the Reorganization Event, the Option confers the right to purchase, for each share of Common Stock subject to the Option immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); provided, however, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise of Options to consist solely of common stock of the acquiring or succeeding corporation (or an affiliate thereof) equivalent in fair market value to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

Notwithstanding the foregoing, if the acquiring or succeeding corporation (or an affiliate thereof) does not agree to assume, or substitute for, such Options, then the Board shall, upon written notice to the Participants, provide that all then unexercised Options will become exercisable in full as of a specified time prior to the Reorganization Event and will terminate immediately prior to the consummation of such Reorganization Event, except to the extent exercised by the Participants before the consummation of such Reorganization Event; provided, however, that in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share of Common Stock surrendered pursuant to such Reorganization Event (the "Acquisition Price"), then the Board may instead provide that all outstanding Options shall terminate upon consummation of such Reorganization Event and that each Participant shall receive, in exchange therefor, a cash payment equal to the amount (if any) by which (A) the Acquisition Price multiplied by the number of shares of Common Stock subject to such outstanding Options (whether or not then exercisable), exceeds (B) the aggregate exercise price of such Options. To the extent all or any portion of an Option becomes exercisable solely as a result of the first sentence of this paragraph, upon exercise of such Option the Participant shall receive shares

subject to a right of repurchase by the Company or its successor at the Option exercise price. Such repurchase right (1) shall lapse at the same rate as the Option would have become exercisable under its terms and (2) shall not apply to any shares subject to the Option that were exercisable under its terms without regard to the first sentence of this paragraph.

If any Option provides that it may be exercised for shares of Common Stock which remain subject to a repurchase right in favor of the Company, upon the occurrence of a Reorganization Event, any shares of restricted stock received upon exercise of such Option shall be treated in accordance with Section 8(c)(3) as if they were a Restricted Stock Award.

(3) Consequences of a Reorganization Event on Restricted Stock Awards. Upon the occurrence of a Reorganization Event, the repurchase and other rights of the Company under each outstanding Restricted Stock Award shall inure to the benefit of the Company's successor and shall apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to the Common Stock subject to such Restricted Stock Award.

(4) Consequences of a Reorganization Event on Other Awards. The Board shall specify the effect of a Reorganization Event on any other Award granted under the Plan at the time of the grant of such Award.

9. General Provisions Applicable to Awards

(a) Transferability of Awards. Except as the Board may otherwise determine or provide in an Award, Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the life of the Participant, shall be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.

(b) Documentation. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Board Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) Termination of Status. The Board shall determine the effect on an Award of the disability, death, retirement, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award.

(e) Withholding. Each Participant shall pay to the Company, or make provision satisfactory to the Board for payment of, any taxes required by law to be withheld in connection with Awards to such Participant no later than the date of the event creating the tax liability. Except as the Board may otherwise provide in an Award, when the Common Stock is registered

under the Exchange Act, Participants may satisfy such tax obligations in whole or in part by delivery of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their Fair Market Value; provided, however, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income). The Company may, to the extent permitted by law, deduct any such tax obligations from any payment of any kind otherwise due to a Participant.

(f) Amendment of Award. The Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Stock Option to a Nonstatutory Stock Option, provided that the Participant's consent to such action shall be required unless the Board determines that the action, taking into account any related action, would not materially and adversely affect the Participant.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

(i) Deferred Delivery of Shares Issuable Pursuant to an Award. The Board may, at the time any Award is granted, provide that, at the time Common Stock would otherwise be delivered pursuant to the Award, the Participant shall instead receive an instrument evidencing the right to future delivery of Common Stock at such time or times, and on such conditions, as the Board shall specify. The Board may at any time accelerate the time at which delivery of all or any part of the Common Stock shall take place.

10. Miscellaneous

(a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights As Stockholder. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares. Notwithstanding the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to such Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(c) Effective Date and Term of Plan. The Plan shall become effective on the date on which it is adopted by the Board. No Awards shall be granted under the Plan after the completion of ten years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company's stockholders, but Awards previously granted may extend beyond that date.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time.

(e) Authorization of Sub-Plans. The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable blue sky, securities or tax laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to this Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, without regard to any applicable conflicts of law.

GELESIS, INC.

2006 STOCK INCENTIVE PLAN

CALIFORNIA SUPPLEMENT

Pursuant to Section 10(e) of the Plan, the Board has adopted this supplement for purposes of satisfying the requirements of Section 25102(o) of the California Law:

Any Awards granted under the Plan to a Participant who is a resident of the State of California on the date of grant (a "California Participant") shall be subject to the following additional limitations, terms and conditions:

11. Additional Limitations on Options.

(a) Minimum Vesting Rate. Except in the case of Options granted to California Participants who are officers, directors, managers, consultants or advisors of the Company or its affiliates (which Options may become exercisable at whatever rate is determined by the Board), Options granted to California Participants shall become exercisable at a rate of no less than 20% per year over five years from the date of grant; provided, that, such Options may be subject to such reasonable forfeiture conditions as the Board may choose to impose and which are not inconsistent with Section 260.140.41 of the California Code of Regulations.

(b) Minimum Exercise Price. The exercise price of Options granted to California Participants may not be less than 85% of the Fair Market Value of the Common Stock on the date of grant in the case of a Nonstatutory Stock Option or less than 100% of the Fair Market Value of the Common Stock on the date of grant in the case of an Incentive Stock Option; provided, however, that if the California Participant is a person who owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or its parent or subsidiary corporations, the exercise price shall be not less than 110% of the Fair Market Value of the Common Stock on the date of grant.

(c) Maximum Duration of Options. No Options granted to California Participants will be granted for a term in excess of 10 years.

(d) Minimum Exercise Period Following Termination. Unless a California Participant's employment is terminated for cause (as defined in any contract of employment between the Company and such Participant, or if none, in the instrument evidencing the grant of such Participant's Option), in the event of termination of employment of such Participant, he or she shall have the right to exercise an Option, to the extent that he or she was otherwise entitled to exercise such Option on the date employment terminated, as follows: (i) at least six months from the date of termination, if termination was caused by such Participant's death or "permanent and total disability" (within the meaning of Section 22(e)(3) of the Code) and (ii) at least 30 days from the date of termination, if termination was caused other than by such Participant's death or "permanent and total disability" (within the meaning of Section 22(e)(3) of the Code).

(e) Limitation on Repurchase Rights. If an Option granted to a California Participant gives the Company the right to repurchase shares of Common Stock issued pursuant to the Plan upon termination of employment of such Participant, the terms of such repurchase right must comply with Section 260.140.41(k) of the California Code of Regulations.

12. Additional Limitations for Restricted Stock Awards.

(a) Minimum Purchase Price. The purchase price for a Restricted Stock Award granted to a California Participant shall be not less than 85% of the Fair Market Value of the Common Stock at the time such Participant is granted the right to purchase shares under the Plan

or at the time the purchase is consummated; provided, however, that if such Participant is a person who owns stock possessing more than 10% of the total combined voting power or value of all classes of stock of the Company or its parent or subsidiary corporations, the purchase price shall be not less than 100% of the Fair Market Value of the Common Stock at the time such Participant is granted the right to purchase shares under the Plan or at the time the purchase is consummated.

(b) Limitation of Repurchase Rights. If a Restricted Stock Award granted to a California Participant gives the Company the right to repurchase shares of Common Stock issued pursuant to the Plan upon termination of employment of such Participant, the terms of such repurchase right must comply with Section 260.140.42(h) of the California Code of Regulations.

13. Additional Limitations for Other Stock-Based Awards. The terms of all Awards granted to a California Participant under Section 7 of the Plan shall comply, to the extent applicable, with Section 260.140.41 or Section 260.140.42 of the California Code of Regulations.

14. Additional Requirement to Provide Information to California Participants. The Company shall provide to each California Participant and to each California Participant who acquires Common Stock pursuant to the Plan, not less frequently than annually, copies of annual financial statements (which need not be audited). The Company shall not be required to provide such statements to key employees whose duties in connection with the Company assure their access to equivalent information.

15. Additional Limitations on Timing of Awards. No Award granted to a California Participant shall become exercisable, vested or realizable, as applicable to such Award, unless the Plan has been approved by a majority of the Company's stockholders within 12 months before or after the date the Plan was adopted by the Board.

16. Additional Limitations Relating to Definition of Fair Market Value. For purposes of Section 1(b) and 2(a) of this supplement, "Fair Market Value" shall be determined in a manner not inconsistent with Section 260.140.50 of the California Code of Regulations.

17. Additional Restriction Regarding Recapitalizations, Stock Splits, Etc. For purposes of Section 8 of the Plan, in the event of a stock split, reverse stock split, stock dividend, recapitalization, combination, reclassification or other distribution of the Company's securities, the number of securities allocated to each California Participant must be adjusted proportionately and without the receipt by the Company of any consideration from any California participant.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the registration statements (Nos. 333-262672 and 333-267016) on Form S-1 and (No. 333-264748) on Form S-8 of our report dated March 28, 2023 with respect to the consolidated financial statements of Gelesis Holdings, Inc.

/s/ KPMG LLP
Boston, Massachusetts
March 28, 2023

Exhibit 31.1

CERTIFICATION

I, Yishai Zohar, certify that:

1. I have reviewed this Annual Report on Form 10-K of Gelesis Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2023

By: /s/ Yishai Zohar

Yishai Zohar
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Elliot Maltz, certify that:

1. I have reviewed this Annual Report on Form 10-K of Gelesis Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2023

By: /s/ Elliot Maltz

Elliot Maltz
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report on Form 10-K of Gelesis Holdings, Inc. (the "Company") for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2023

By: /s/ Yishai Zohar

Yishai Zohar
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report on Form 10-K of Gelesis Holdings, Inc. (the "Company") for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2023

By: /s/ Elliot Maltz

Elliot Maltz
Chief Financial Officer
(Principal Financial and Accounting Officer)