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 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: 000-51173

Catalyst Biosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**56-2020050**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
611 Gateway Blvd. Suite 710 South San Francisco, California	**94080**
(Address of Chief Executive Offices)	**(Zip Code)**

(650) 871-0761
(Registrant's Telephone Number, Including Area Code)

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	CBIO	NASDAQ

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 Section 15(d) of the Securities Exchange 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, a 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 Securities Exchange Act). Yes ☐ No ☒

As of March 24, 2023, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 37,759,825. The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2022, was $55,642,222.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's proxy statement for its 2023 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed with the U.S. Securities and Exchange Commission, no later than 120 days after the Registrant's fiscal year ended December 31, 2022, are incorporated by reference to Part III of this Annual Report on Form 10-K.

CATALYST BIOSCIENCES, INC.
Annual Report on Form 10-K
TABLE OF CONTENTS

PART I

Forward-Looking Statements and Market Data

This Annual Report on Form 10-K and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements, other than statements of historical facts, included or incorporated by reference in this Annual Report on Form 10-K regarding our strategy, future results of operations, future financial condition, future revenues, projected costs, prospects, plans, intentions and objectives of management, as well as the assumptions that underlie these statements, are forward-looking statements. These forward-looking statements should not be relied upon as predictions of future events as Catalyst Biosciences, Inc. and its subsidiary (the "Company" or "Catalyst") cannot assure you that the events or circumstances reflected in these statements will be achieved or will occur. Forward-looking statements are identified by words such as "believes," "expects," "may," "will," "should," "seeks," "intends," "plans," "pro forma," "estimates," or "anticipates" or the negative of these words and phrases or other variations of these words and phrases or comparable terminology, although not all forward-looking statements contain these identifying words. Such forward-looking statements are based on our management's assumptions and assessments in light of information currently available to our management, its experience and its perception of historical trends, current conditions, expected future developments and other factors our management believes to be appropriate.

You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. For example, forward-looking statements include any statements regarding:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other positive results;
- our ability to develop a pipeline of product candidates to address unmet needs in the treatment of organ fibrosis and other inflammatory diseases;
- the timing, progress and results of clinical trials for Hydronidone from Catalyst's Phase 2a trial and other product candidates Catalyst may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the studies or trials will become available and research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including timing of INDs and final FDA approval of Hydronidone for the treatment of NASH and liver fibrosis associated with CHB, and any other future product candidates;
- the timing, scope or likelihood of foreign regulatory filings and approvals;
- Catalyst's expectations regarding the reconsideration of its strategic alternatives in the event the Business Combination is not completed;
- Catalyst's expectations regarding the future pursuit of product development efforts, including whether it will pursue such efforts, estimates regarding the expenses, future revenue, timing of any future revenue, capital requirements and need for additional financing related to such efforts, the timing of and ability of Catalyst to pursue such efforts and Catalyst's plans to develop and, if approved, subsequently commercialize any product candidates resulting from such efforts;
- Catalyst's expectations regarding its ability to fund its operating expenses and capital expenditure requirements with its cash, cash equivalents and investments;
- our ability to develop and advance current product candidates and programs into, and successfully complete, clinical studies;
- our manufacturing, commercialization and marketing capabilities and strategy;
- plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;

- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidates, including estimates of the number of patients who suffer from the diseases Catalyst is targeting;
- expectations regarding the approval and use of our product candidates in combination with other drugs;
- expectations regarding potential for accelerated approval or other expedited regulatory designation;
- our competitive position and the success of competing therapies that are or may become available;
- estimates of the number of patients that the Company will enroll in its clinical trials;
- the beneficial characteristics and the potential safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of its product candidates and its expectations regarding particular lines of therapy;
- plans relating to the further development of our product candidates, including additional indications Catalyst may pursue;
- existing regulations and regulatory developments in the United States, Europe, and other jurisdictions;
- expectations regarding the impact of the COVID-19 pandemic on our business;
- our intellectual property position, including the scope of protection Catalyst is able to establish and maintain for intellectual property rights covering Hydronidone, and other product candidates it may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates and for the manufacture of its product candidates for clinical trials;
- our relationships with patient advocacy groups, key opinion leaders, regulators, the research community and payors;
- our ability to obtain and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of Hydronidone, and other product candidates the Company may develop, if approved;
- the rate and degree of market acceptance and clinical utility of Hydronidone, and other product candidates the Company may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the period over which Catalyst estimates its existing cash and cash equivalents will be sufficient to fund its planned operating expenses and capital expenditure requirements;
- statements regarding the approval and closing of the Business Combination;
- the timing of the consummation of the Business Combination;
- Catalyst's ability to solicit a sufficient number of proxies to approve the change of control resulting from the Business Combination;
- satisfaction of conditions to the completion of the Business Combination;
- the expected benefits of the Business Combination;

- Catalyst's ability to complete the Business Combination;
- expectations about the continued listing of Catalyst Common Stock on The Nasdaq Capital Market;
- the impact of laws and regulations; and
- expectations regarding the period during which Catalyst will qualify as a smaller reporting company under the Exchange Act.

Any such forward-looking statements are not guarantees of future performance and are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in or contemplated by such forward-looking statements. Factors that might cause such a difference include, but are not limited to, the risks and uncertainties described in this Annual Report on Form 10-K, including those risks described in Part I, Item 1A, "Risk Factors," as well as others that it may consider immaterial or do not anticipate at this time. The risks and uncertainties described in this report, including in Part I, Item 1A, "Risk Factors," are not exclusive and further information concerning our company and our businesses, including factors that potentially could materially affect our operating results or financial condition, may emerge from time to time. All forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and Catalyst undertake no obligation to update or revise these statements considering future developments. The Company cautions investors that our business and financial performance are subject to substantial risks and uncertainties and they should carefully consider the factors set forth in other reports or documents that Catalyst files from time to time with the Securities and Exchange Commission (the "SEC").

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, Catalyst obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, the Company does not expressly refer to the sources from which this data is derived. In that regard, when Catalyst refers to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Item 1. BUSINESS.

Summary

Catalyst Biosciences, Inc., together with its subsidiary ("Catalyst"), is a biopharmaceutical company focused on the development and commercialization of Hydronidone for the treatment of NASH (nonalcoholic steatohepatitis, a severe form of nonalcoholic fatty liver disease) in the United States. Hydronidone is being evaluated for the treatment of liver fibrosis associated with a broad spectrum of chronic liver diseases. A Phase 1 clinical trial of Hydronidone has been completed in the United States and generated pharmacokinetic ("PK"), safety and tolerability data of single and multiple ascending doses of Hydronidone in U.S. healthy subjects.

Overview

Prior to ceasing research and development activities in March 2022, Catalyst had engineered several protease assets that were designed to address unmet medical needs in disorders of the complement or coagulation systems. Prior to the F351 Agreement (as defined below), Catalyst had engaged in the research and development of product candidates from Catalyst's protein engineering platform. In February 2022, Catalyst announced that it engaged Perella Weinberg Partners as a financial advisor to assist Catalyst in exploring strategic alternatives to monetize its assets.

In March 2022, Catalyst ceased research and development activities and in May 2022, Catalyst entered into an asset purchase agreement with Vertex Pharmaceuticals Inc. ("Vertex"), pursuant to which Vertex purchased Catalyst's complement portfolio, including CB 2782-PEG and CB 4332, as well as its complement-related intellectual property, including the ProTUNE™ and ImmunoTUNE™ platforms, for $60.0 million in cash consideration. $55.0 million was received upfront and the remaining $5.0 million was retained by Vertex as a hold-back until one year after the closing date to satisfy certain post-closing indemnification obligations. Any amounts received from Vertex with respect to this hold-back will be distributed to holders of the contingent value right issued to Catalyst stockholders of record on January 5, 2023.

On September 20, 2022, the Company paid a special, one-time cash dividend payment of $1.43 per share, or approximately $45.0 million, to holders of our common stock.

On December 26, 2022, Catalyst executed an Asset Purchase Agreement, dated December 26, 2022 (the "F351 Agreement"), with GNI Group Ltd. and GNI Hong Kong Limited (together "GNI") to purchase all of the assets and intellectual property rights primarily related to GNI's proprietary Hydronidone compound (collectively, the "F351 Assets"), other than such assets and intellectual property rights located in the People's Republic of China. At the closing of the agreement on December 26, 2022, it paid GNI $35.0 million in the form of 6,266,521 shares of our common stock and 12,340 shares of a newly designated series of preferred stock ("Catalyst Convertible Preferred Stock"). Each share of Catalyst Convertible Preferred Stock is convertible into 10,000 shares of common stock, subject to stockholder approval under Nasdaq rules and subject to a beneficial ownership conversion blocker.

On December 26, 2022, Catalyst, GNI USA, Inc., a Delaware corporation ("GNI USA"), GNI Japan, GNI Hong Kong, Shanghai Genomics, Inc., a company organized under the laws of the People's Republic of China ("SG" and collectively with GNI USA, GNI Japan and GNI Hong Kong, "Contributors," and each a "Contributor"), the individuals (each, a "Minority Holder" and collectively, the "Minority Holders") listed on an annex to that certain Business Combination Agreement, as amended (the "Business Combination Agreement") and Continent Pharmaceuticals Inc., a Cayman Islands company limited by shares ("CPI"), entered into the Business Combination Agreement. The Business Combination Agreement contains the terms and conditions of the proposed business combination pursuant to which Catalyst will acquire an indirect controlling interest in Beijing Continent Pharmaceuticals Co., Ltd, a company organized under the laws of the People's Republic of China ("BC"). Pursuant to the Business Combination Agreement, (a) GNI USA will contribute all of its ordinary shares in the capital of CPI, par value $0.0001 per share (each a "CPI Ordinary Share") to Catalyst in exchange for 688,850,101 shares of Catalyst common stock, par value $0.001 per share (the "Catalyst Common Stock") (the "CPI Contribution"), (b) GNI USA will contribute its interest in Further Challenger International Limited, a company incorporated and existing under the laws of the British Virgin Islands with company number 1982271 ("Further Challenger"), to Catalyst in exchange for 264,971,695 shares of Catalyst Common Stock (the "FC Contribution") and (c) each Minority Holder will contribute 100% of the interest he or she holds in his or her respective Entity (as defined in the Business Combination Agreement) to Catalyst in exchange for an aggregate of 156,954,428 shares of Catalyst Common Stock in the amounts set forth

on an annex to the Business Combination Agreement (the "Minority Holder Contributions" and together with the CPI Contribution and the FC Contribution, the "Contributions"). At the election of GNI USA or any Minority Holder, GNI USA or such Minority Holder shall be issued shares of Catalyst Convertible Preferred Stock in lieu of some or all of the shares of Catalyst Common Stock GNI USA or such Minority Holder is entitled to receive. Catalyst expects that the transactions under the Business Combination Agreement (the "Transactions") will close in the third quarter of 2023, subject to obtaining necessary stockholder approvals.

In accordance with the Business Combination Agreement, on December 26, 2022, Catalyst and the Rights Agent (as defined therein) executed a contingent value rights agreement (the "CVR Agreement"), pursuant to which each holder of our common stock as of January 5, 2023 ("CVR Holders"), received one contractual contingent value right ("CVR") issued by us, subject to and in accordance with the terms and conditions of the CVR Agreement, for each share of our common stock held by such holder. Each CVR entitles the holder thereof to receive (i) certain cash payments from the net proceeds related to the disposition of our legacy assets (MarzAA, DalcA, and CB 2679d-GT), (ii) 100% of the excess cash (net of all current or contingent liabilities, including transaction-related expenses) retained by us in excess of $1.0 million as of the closing date of the Business Combination Agreement, (iii) 100% of the amount actually received by us pursuant to the Vertex asset purchase agreement, and (iv) 100% of the excess, by which the preapproved costs to manage, negotiate, settle and finalize certain third party claims exceed the costs actually incurred with respect to such claims. Catalyst anticipates one or more additional distributions to the holders of the CVRs in the future, although there can be no assurance as to the timing or amounts of any distributions it makes. The actual amount of any distributions will depend on many factors, including, without limitation, the timing of any distributable proceeds to Catalyst and the costs and expenses for activities related to those distributions.

On December 27, 2022, Catalyst declared another special cash dividend of $0.24 per share, or approximately $7.6 million, to holders of our common stock, excluding GNI, which was paid on January 12, 2023.

On February 27, 2023, Catalyst signed an asset purchase agreement with GC Biopharma Corp. ("GCBP") pursuant to which GCBP acquired Catalyst's legacy rare bleeding disorders programs including marzeptacog alpha activated ("MarzAA"), dalcinonacog alpha ("DalcA") and CB-2679d-GT for a total of $6.0 million, $1.0 million payable on signing and $5.0 million payable on February 28, 2025, subject to satisfaction of post-closing indemnification obligations. In March 2023, Catalyst distributed net proceeds of approximately $0.2 million to the CVR Holders. Once received, any additional net proceeds from the transaction will be distributed to the CVR Holders.

Catalyst is also pursuing certain legal claims against a third party related to payments under a 2016 asset purchase agreement, and any net recoveries related to these claims will be distributed to the CVR Holders.

Current Product Development Plans

Catalyst anticipates filing an IND application for the treatment of NASH in the United States in late 2023. NASH is a severe form of nonalcoholic fatty liver disease ("NAFLD"), characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, HCC and death. There are currently no approved products for the treatment of NASH.

Hydronidone is a structural analogue of the approved anti-fibrotic (pulmonary fibrosis) drug pirfenidone. Hydronidone has been shown to inhibit *in vitro* both p38γ kinase activity and TGF-ß1-induced excessive collagen synthesis in hepatic stellate cells ("HSCs"),which are recognized as critical events in the development and progression of fibrosis in the liver. This is further supported by its anti-proliferative effects on the HSCs in the liver. *In vitro* anti-fibrotic effects of Hydronidone were also confirmed in several established *in vivo* rodent models of liver fibrosis such as carbon tetrachloride ("CCl_4")-induced liver fibrosis mouse model, DMN-induced liver fibrosis rat model, and HSA-induced liver fibrosis rat model, as well as mouse model of NASH fibrosis (CCl_4 +Western [High Fat] Diet). In the NASH mouse model, Hydronidone significantly reduced the severity of liver fibrosis, as well as demonstrating improvement in functional, biochemical and histopathological attributes of the affected liver tissue, including significant reduction of hydroxyproline content and liver enzymes (ALT), aspartate (AST), decrease in liver fatty degeneration, and levels of a spectrum of inflammatory cytokines, at doses 3-10 mg/kg/day, as well as decrease in NAS score and the CCl_4 and western diet ("WD")-induced fibrosis and cell ballooning in NASH model at doses of 15-50 mg/kg bid (HEDs of 144 – 480 mg) which are relevant to human exposure. Thus, the key attributes of

Hydronidone's molecular mechanisms of action in animal models of liver fibrosis, support its efficacy potential in liver fibrosis of various etiologies including those associated with NASH.

Catalyst plans to initiate clinical development of Hydronidone in NASH fibrosis in a randomized, double-blind, placebo-controlled, parallel group, Phase 2a, PoC clinical study evaluating the safety, tolerability, PK, and Pharmacodynamics ("PD") of Hydronidone capsules administered daily at an oral dose of 360 mg (given as 120 mg TID) for 24 weeks to adult subjects with advanced liver fibrosis associated with noncirrhotic NASH. The main goal of the proposed Phase 2a study is to obtain early PoC for Hydronidone in subjects with NASH fibrosis as a basis of expansion into a more comprehensive Phase 2/3 clinical program. The study will include a small sample size (total of 60 evaluable subjects) who will receive in a 2:1 ratio Hydronidone or Placebo. A single dose level that was shown to be safe and effective in a 52-week clinical study in Chinese subjects with advanced fibrosis associated with chronic Hepatitis B ("CHB") infection will be used. The study will evaluate trends of changes from baseline in a set of noninvasive biochemical and imaging biomarkers relevant to assessment of NASH fibrosis in the context of drug exposure, as well as the mechanism of anti-fibrotic action of Hydronidone. The study will include PK blood sampling and assessment of the initial population PK and preliminary PK/PD relationship to inform Hydronidone treatment in future clinical studies in NASH fibrosis. In addition, this trial will include a disease-specific PROs, a validated composite CLDQ – NASH, to collect patient-reported data about the impact of Hydronidone treatment on quality of life of subjects with advanced NASH fibrosis.

NASH represents a large and rapidly growing problem in the United States and worldwide. Diagnoses have been on the rise and are expected to increase dramatically in the next decade. The prevalence of NAFLD, which affects approximately 25% of the global population, and NASH, which develops in approximately 20% to 25% of NAFLD patients, is driven primarily by the worldwide obesity epidemic. As a result, the prevalence of NASH has increased significantly in recent decades, paralleling similar trends in the prevalence of obesity, insulin resistance and Type 2 diabetes. The prevalence of these conditions is expected to increase further in view of the unhealthy nutrition habits, such as consumption of a diet high in fructose, sucrose and saturated fats, and sedentary behavior that characterize modern lifestyle.

Hydronidone is a structural analogue of the approved drug pirfenidone. Hydronidone has been shown to inhibit in vitro both p38γ kinase activity and TGF-ß1-induced excessive collagen synthesis in HSCs, which are recognized as critical events in the development and progression of fibrosis in the liver. This is further supported by its anti-proliferative effects on the HSCs in the liver. The key attributes of Hydronidone's molecular mechanisms of action in animal models of liver fibrosis included that of NASH, support its efficacy potential in liver fibrosis of various etiologies including that associated with NASH. Hydronidone has exhibited protective effects on CCl4+WD induced NASH; the total NAS and fibrosis scores were statistically significantly lower following Hydronidone dosing at 15-50 mg/kg/day.

In the NASH mouse model, Hydronidone significantly reduced the severity of fibrosis, as well as demonstrating improvement in functional, biochemical and histopathological attributes of the affected liver tissue, including significant reduction of hydroxyproline content and liver enzymes (ALT, AST), decrease in liver fatty degeneration, and levels of a spectrum of inflammatory cytokines, at doses 3-10 mg/kg/day, as well as decrease in NAS score and the CCl_4 and WD-induced fibrosis and cell ballooning in NASH model at doses of 15-50 mg/kg bid (HEDs of 144 – 480 mg) which are relevant to human exposure.

In preclinical studies, the key attributes of Hydronidone's molecular mechanisms of action in animal models of liver fibrosis included that of NASH, support its efficacy potential in liver fibrosis of various etiologies including that associated with NASH. To support the indication of NASH-associated fibrosis, GNI USA evaluated the anti-fibrotic effects of Hydronidone in a murine NASH model which is characterized by a rapid progression of extensive liver fibrosis. The model was induced by feeding male C57BL/6J mice (n=20/group) a high fat diet for 14 weeks. Subcutaneous injections of CCl_4 in weeks 11-14 served as an accelerator of the liver pathology and exacerbated histological features of NASH and associated fibrosis. The establishment of the NASH model was indicated by statistically significantly higher body weights, lower food intake, and histopathologically observed fatty degeneration, inflammatory infiltrates, and hepatocellular ballooning in NASH mice *vs* negative control. The NAS total score, ballooning, and steatosis score in the NASH mice (positive control, model) group increased significantly compared to Naive (negative control group). Hydronidone exhibited protective effect on CCl_4+WD induced NASH; the total NAS and fibrosis score were statistically significantly lower following Hydronidone dosing at 15-50 mg/kg/day. Fibrosis

and cell ballooning were significantly inhibited by Hydronidone, but no effects on inflammation and steatosis were observed. Hydronidone performed better than Pirfenidone in this model, at comparable dose.

On February 27, 2023, the Company signed an asset purchase agreement with GC Biopharma ("GCBP") pursuant to which GCBP acquired the Company's legacy rare bleeding disorders programs including MarzAA, DalcA and CB-2679d-GT for a total of $6 million, $1 million payable on signing and $5 million payable on February 28, 2025, subject to satisfaction of post-closing indemnification obligations. In March 2023, Catalyst distributed net proceeds of approximately $206,000 to the CVR Holders. Once received, any additional net proceeds from the transaction will be distributed to the CVR Holders. Catalyst is also pursuing certain legal claims against a third party related to payments under a 2016 asset purchase agreement, and any net recoveries related to these claims will be distributed to the CVR Holders.

Catalyst is located in South San Francisco, California and operates in one segment.

Disease Overview - NASH

NASH, a severe form of NAFLD, is characterized histologically by the additional presence of inflammation and hepatocellular injury, such as visible ballooning, and has a significantly worse prognosis, with the potential to progress to liver fibrosis, cirrhosis or HCC.

NASH represents a large and rapidly growing problem in the United States and worldwide. Diagnoses have been on the rise and are expected to increase dramatically in the next decade. The prevalence of NAFLD, which affects approximately 25% of the global population, and NASH, which develops in approximately 20% to 25% of NAFLD patients, is driven primarily by the worldwide obesity epidemic. As a result, the prevalence of NASH has increased significantly in recent decades, paralleling similar trends in the prevalence of obesity, insulin resistance and Type 2 diabetes. The prevalence of these conditions is expected to increase further due to unhealthy nutrition habits, such as consumption of a diet high in fructose, sucrose and saturated fats, and sedentary behavior.

The critical pathophysiologic mechanisms underlying the development and progression of NASH include reduced ability to metabolize and clear lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. NASH patients have an excessive accumulation of fat in the liver resulting primarily from a caloric intake above and beyond energy needs. A healthy liver contains less than 5% fat, but a liver in someone with NASH can contain more than 20% fat. This abnormal liver fat contributes to the progression to NASH, a liver necro-inflammatory state, that can lead to scarring, also known as fibrosis, and, for some, can progress to cirrhosis and liver failure—cirrhosis develops in approximately 20% to 45% of patients. In some cases, cirrhosis progresses to decompensated cirrhosis, which results in permanent liver damage that can lead to liver failure. In addition, it is estimated that 8% of patients with advanced fibrosis will develop HCC. NASH is a complex, multifaceted disease that does not just affect the liver. Patients with NASH frequently have other significant metabolic co-morbidities such as obesity, hyperglycemia, dyslipidemia and systemic hypertension (a constellation of which is commonly referred to as metabolic syndrome) and these further contribute to the risk of cardiovascular disease.

Etiology of NASH

Understanding of the pathophysiologic mechanisms that lead to NASH has evolved in recent years. Excessive caloric overload, metabolic dysregulation, cardio-metabolic co-morbidities and genetic risk factors increase the likelihood of developing NASH, with a multitude of potential mechanistic contributors to pathophysiology. In NASH, the liver's capacity to handle the primary metabolic energy substrates, carbohydrates and fatty acids, is overwhelmed. This occurs when there is an excess of free fatty acids deposited in the liver or their disposal from the liver is impaired. The accumulation of surplus free fatty acids leads to the formation of toxic lipid species. These toxic lipids then induce endoplasmic reticulum stress, oxidative stress and an inflammatory response, which can result in hepatocellular injury and death. This may lead to fibrosis and genomic instability, which may worsen over time to cirrhosis and HCC, respectively.

The critical pathophysiologic mechanisms underlying development and progression of NASH include (1) reduced ability to handle lipids, (2) increased insulin resistance, (3) injury to hepatocytes and (4) development and progression of liver fibrosis in response to hepatocyte injury.

Diagnosis

Most people with NASH are asymptomatic and their disease is often discovered incidentally following a liver imaging procedure, such as an ultrasound, prescribed for other reasons or as part of an investigation for elevated liver enzymes. Once suspected clinically, a liver biopsy is required to definitively diagnose NASH, which necessitates the joint presence of steatosis, ballooning and lobular inflammation. Once pathologically confirmed, the severity of NAFLD and NASH is determined using the histologically validated NAS, which grades disease activity on a scale of 0 to 8. The NAS is the sum of the individual scores for steatosis (0 to 3), lobular inflammation (0 to 3), and hepatocellular ballooning (0 to 2) but does not include a score for fibrosis. Fibrosis staging (F0-F4) relies on the Kleiner classification (F0 = no fibrosis; F1 = perisinusoidal or periportal fibrosis (not both); F2 = both perisinusoidal and periportal fibrosis; F3 = bridging fibrosis; F4 = cirrhosis).

Histological diagnosis remains the gold standard for assessment of NASH and fibrosis. However, given that liver biopsy is associated with risks of pain, bleeding and other morbidity, as well as significant cost, the procedure is not practical for general patient screening. Additionally, histology diagnosis is confounded by evaluation of a small sliver of a large heterogenous organ that may not represent the full organ, and significant variability in reading of slides including inter- and intra-reader variability. Several non-invasive tools such as clinical risk scores, serum markers and imaging techniques are increasingly used to assess NASH patients. Non-invasive tests ("NITs") such as the Fibroscan-AST score, Fibrosis-4 index, the Enhanced Liver Fibrosis score and vibration-controlled transient elastography, have been validated and are increasingly used. These NITs have an excellent negative predictive value and an acceptable positive predictive value for detection of advanced (≥ F3) fibrosis and are increasingly used in clinical settings. Additionally, evidence is emerging that shows a correlation between reduction in steatosis as measured by MRI-proton density fat fraction (MRI-PDFF) and reduction in ALT ≥17 U/L and histologic improvement on liver biopsy. In draft guidance, the FDA encouraged sponsors to identify biochemical or noninvasive imaging biomarkers that, once characterized and agreed by the FDA, could replace liver biopsies for patient selection and efficacy assessment in clinical trials.

We expect that the validation and subsequent adoption of these NITs will result in an increase in the diagnosis and treatment rates for NASH in the future.

Hydronidone Overview

Hydronidone, Catalyst's phase 1 clinical-stage drug, has the potential to treat NASH. To date, there are no approved products for the treatment of NASH. The phase 1 clinical trial results have demonstrated Hydronidone's potential efficacy in the reversal of the fibrosis process. Hydronidone may reverse liver fibrosis by inhibiting hepatic stellate cell proliferation and the TGF-ß1 signaling pathway, both of which play major roles in the liver fibrosis associated with NASH.

Mechanism of Action

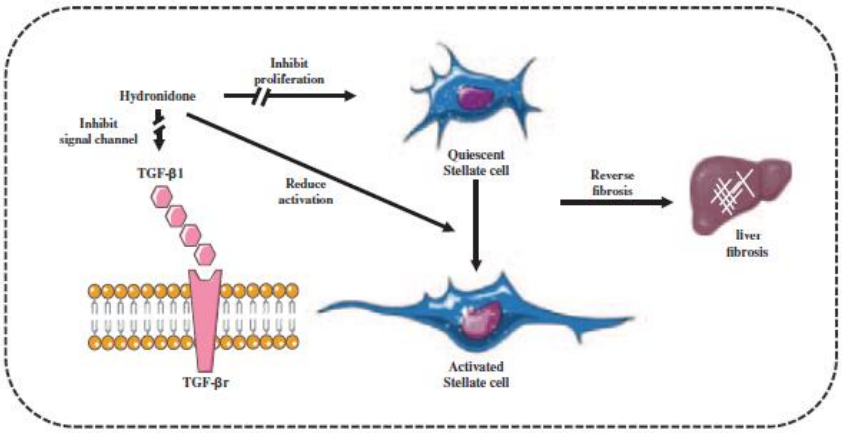
Hydronidone is a structural analogue of the approved drug pirfenidone. Hydronidone has been shown to inhibit both p38γ kinase activity and TGF-ß1-induced excessive collagen synthesis *in vitro* in HSCs, which are recognized as critical events in the development and progression of fibrosis in the liver. This is further supported by its anti-proliferative effects on the HSCs in the liver.

In vitro anti-fibrotic effects of Hydronidone were also confirmed in several established *in vivo* models of liver fibrosis such as CCl_4-induced liver fibrosis mouse model, DMN-induced liver fibrosis rat model, and HSA-induced liver fibrosis rat model, as well as mouse model of NASH fibrosis (CCl_4 +Western [High Fat] Diet).

In the NASH mouse model, Hydronidone significantly reduced the severity of fibrosis, as well as demonstrating improvement in functional, biochemical and histopathological attributes of the affected liver tissue, including significant reduction of hydroxyproline content and liver enzymes (ALT, AST), decrease in liver fatty degeneration, and levels of a spectrum of inflammatory cytokines, at doses 3-10 mg/kg/day, as well as decrease in NAS score and the CCl_4 and WD-induced fibrosis and cell ballooning in NASH model at doses of 15-50 mg/kg bid (HEDs of 144 – 480 mg) which are relevant to human exposure.

Thus, the key attributes of Hydronidone's molecular mechanisms of action in animal models of liver fibrosis support its efficacy potential in liver fibrosis of various etiologies, including those associated with NASH.

The diagram below illustrates the mechanism of action of Hydronidone:

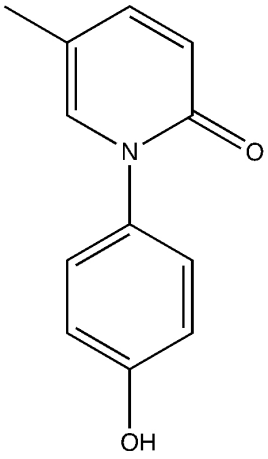


Source: Company data, Frost & Sullivan

Biological Effects of Hydronidone

Hydronidone is a new chemical entity, structural analogue of an approved anti-fibrotic drug, pirfenidone. The chemical structure and formula of Hydronidone are presented below.

N-(4-hydroxyphenyl)-5-methyl-2-pyridone



C12H11NO2

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Hydronidone Pre-Clinical Development in NASH

Phase 1

The primary objective of this study was to assess the PK of Hydronidone capsules when administered as single and repeated doses to healthy adult volunteers, and the secondary objective was to evaluate the safety and tolerability of Hydronidone capsules following single and multiple dose oral administrations to healthy adult volunteers. This was an open-label, two-part study. Part I was a single escalating dose, sequential cohort study of oral capsules of Hydronidone 30 mg and Hydronidone 120 mg. Part II was a multiple escalating dose, sequential cohort study of oral capsules of Hydronidone 30 mg TID for seven days and Hydronidone 120 mg TID for seven days. In Part II, subjects received an extra dose on the morning of Study Day 8.

Following single oral doses of Hydronidone 30 mg or 120 mg in Part I of the study, Hydronidone was rapidly absorbed showing a linear PK pattern of exposure, with mean elimination half-life of Hydronidone was 5 to 6 hours, and was 5 to 7 hours for M3 and M4 metabolites. Following repeated oral doses of Hydronidone 30 mg or 120 mg TID for seven days in Part II of the study, Hydronidone capsules were rapidly absorbed with similar PK pattern of exposure as seen following single doses of Hydronidone and similar half-life. Modest accumulation (less than 1.5-fold increase) was observed for Hydronidone, M3 and M4 with repeated 30 mg or 120 mg TID. Dose-normalized Hydronidone C_{max} and AUC values were similar in males and females.

Overall, Hydronidone was well tolerated when administered as a single oral dose of 30 mg or 120 mg and when administered as repeated oral doses of 30 mg or 120 mg TID for 7 days (22 total doses). There were no premature discontinuations due to adverse events (“AEs”), no serious adverse events (“SAEs”) nor deaths reported in this study. Treatment-emergent AEs reported following single dose administration in Part I of the study included a single AE of rhinorrhoea and scattered, isolated, reversible laboratory abnormalities. Treatment-emergent AEs reported following repeated dose administration in Part II of the study included headache (25.0%), constipation (16.7%) and somnolence (12.5%). Abdominal discomfort and flatulence were also reported as GI AEs in 1 subject each. Scattered, isolated, reversible or stable laboratory abnormalities were reported in 1 or 2 subjects. There were no clinically significant overall changes in safety laboratory tests that were attributable to study drug, including no evidence of any significant drug-induced liver injury, nor clinically significant overall changes in vital signs, ECG parameters or physical examinations that were attributable to study drug.

Phase 2

To support the IND filing and initiation of the proposed Phase 2a clinical study, Catalyst plans to cross-reference all clinical data obtained in studies currently completed under the IND, as well as those completed in the PRC. Specifically, the initiation of this clinical study is supported by the completed Phase 1 study bridging safety, tolerability, and PK in the United States in healthy subjects (single and multiple dosing), and the recently completed 52-week Phase 2 clinical study of Hydronidone in Chinese subjects with liver fibrosis associated with CHB infection conducted by BC. Catalyst believes that the results obtained in these studies provide adequate information on the current clinical risk/benefit profile of the drug and allow for safe initiation of the proposed Phase 2a clinical study of Hydronidone in NASH associated fibrosis.

Catalyst plans to initiate clinical development of Hydronidone in NASH fibrosis in a randomized, double-blind, placebo-controlled, parallel group, Phase 2a, Proof-of-Concept (“PoC”) clinical study evaluating the safety, tolerability, PK, and Pharmacodynamics (“PD”) of Hydronidone capsules administered daily at an oral dose of 360

mg (given as 120 mg TID) for 24 weeks to adult subjects with advanced liver fibrosis associated with noncirrhotic NASH. The main goal of the proposed Phase 2a study is to obtain early PoC for Hydronidone in subjects with NASH fibrosis as a basis of expansion into a more comprehensive Phase 2/3 clinical program. The study population will be further characterized by inclusion and exclusion criteria at baseline, which will include, among the others, serum biomarkers (*i.e.*, NAFLD scoring) and imaging modality, such as LSM via FibroScan. Magnetic Resonance Elastography may be evaluated in a selected number of subjects as an exploratory measure. The cut-offs of both non-invasive biomarkers as well as elastography will be consistent with identifying patients with advanced fibrosis while separating them from those indicative of cirrhosis.

The proposed severity of fibrosis will allow more space for separation from placebo, if any. It has been shown that more severe fibrosis responds favorably to Hydronidone in the clinical trial of Hepatitis B-associated liver fibrosis, without significant safety concerns. In addition, these patients are at high risk for progression to cirrhosis without adequate treatment options, and as such, they are a suitable population for treatment with Hydronidone.

Agreements Relating to the Hydronidone Program

F351 Asset Purchase Agreement

On December 26, 2022, Catalyst acquired the F351 Assets from the GNI Japan and GNI Hong Kong. Pursuant to the F351 Agreement, Catalyst acquired all of the assets and intellectual property rights primarily related to GNI Japan's and GNI Hong Kong's proprietary Hydronidone compound, other than such assets and intellectual property rights located in the PRC. The F351 Assets include 15 issued or pending patents and patent applications outside of the PRC, with the last acquired issued patent expected to expire in August 2037.

Under the terms of the F351 Agreement and upon the effective time of the transactions contemplated by the F351 Agreement, Catalyst paid GNI Japan and GNI Hong Kong $35,000,000 in the form of: 6,266,521 shares of Catalyst Common Stock; and 12,340 shares of Catalyst Convertible Preferred Stock.

Competition

The biopharmaceutical industry is intensely competitive and subject to rapid innovation and significant technological advancements. We believe the key competitive factors that will affect the development and commercial success of Hydronidone and any future product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price, the level of generic competition and reimbursement. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies, universities and other research institutions. A number of biotechnology and pharmaceutical companies are pursuing the development or marketing of pharmaceuticals that target the same diseases that we are targeting. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Given the high incidence of NASH, it is likely that the number of companies seeking to develop products and therapies for the treatment of liver and cardio-metabolic diseases, such as NASH, will increase.

If Hydronidone is approved for the treatment of NASH, future competition could also arise from select products currently in development, including: Firsocostat/GS-0976, an ACC inhibitor, and Cilofexor/GS-9674, an FXR agonist, from Gilead Sciences, Inc.; Clesacostat/PF-05221304, an ACC inhibitor, and PF-06835919, a KHK inhibitor, from Pfizer Inc.; Ocaliva, an FXR agonist from Intercept Pharmaceuticals, Inc.; Resmetirom, a beta-thyroid hormone receptor agonist from Madrigal Pharmaceuticals, Inc.; VK2809, a beta-thyroid hormone receptor agonist from Viking Therapeutics, Inc.; Aldafermin, an FGF19 analog from NGM Biopharmaceuticals, Inc.; MK-3655, an FGFR1c/KLB agonist antibody from Merck & Co., Inc.; Efruxifermin, a FGF21 fusion protein from Akero Therapeutics, Inc.; Pegozafermin, a FGF21 fusion protein from 89bio, Inc.; Belapectin, a Galectin-3 inhibitor from Galectin Therapeutics Inc.; Aramchol, a synthetic conjugate of cholic acid and arachidic acid from Galmed Pharmaceuticals Ltd.; Semaglutide, a GLP-1 receptor agonist from Novo Nordisk A/S; Pemvidutide/ALT-801, a dual GLP-1/glucagon agonist from Altimmune; Tirzepatide, a dual GIP/GLP-1 receptor agonist from Eli Lilly and Company; Lanifibranor, a PPAR alpha/delta/gamma agonist from Inventiva; NNC0194-0499, an FGF21 analog from Novo Nordisk; BOS-580, an FGF21 analog from Boston Pharmaceuticals; and BFKB8488A, an FGFR1/KLB agonist antibody from Genentech; and pegozafermin, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 from 89bio, Inc.

Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly longer operating histories and greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. As a result, our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop and succeed in obtaining approval for drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and enrolling patients for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Manufacturing and Supply

Currently, the manufacturing of Hydronidone active pharmaceutical ingredients (“API”) and drug product supplies required for supporting the Phase 2a clinical study in NASH is being outsourced to WuXi STA, based in the PRC. The API and drug product will be of cGMP grade quality, and batch release and stability studies will comply with applicable regulatory requirements. Currently, the manufacturing and quality agreements for the Hydronidone API and drug product supplies to support the Phase 2a clinical study in NASH are under negotiation.

Intellectual Property

Our success depends in part upon our ability to protect our core technology and intellectual property. Our intellectual property is critical to our business and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, new targets, indications and applications and other inventions important to our business. For our product candidates, we generally pursue patent protection covering compositions of matter, methods of manufacture and methods of use. As we further develop our product candidates, we plan to identify additional novel candidates for patent protection that may potentially enhance commercial success, including pursuit of claims directed to new therapeutic indications.

Hydronidone Patents

Our Hydronidone patent portfolio currently consists of five (5) patent families, including patents and/or patent applications in the United States, the Patent Cooperation Treaty, the European Patent Convention and Japan.

The first patent family is entitled “DERIVATIVES OF PYRIDONE AND THE USE OF THEM”. The patent family provides granted patent protection in six countries, including the United States (U.S. Patent Number 7,824,133, expiry date: September 22, 2024; U.S. Patent Numbers 8,022,087 and 8,084,465, expiry dates: November 14, 2023), Japan (JP Patent Number 4614884, expiry date: November 14, 2023), and Germany (DE Patent Number 60340364, expiry date: November 14, 2023). The granted claims protect our lead drug candidate Hydronidone and pharmaceutical compositions thereof, as well as methods for preparing or using Hydronidone to treat fibrosis.

The second patent family is entitled “USE OF PYRIDONE DERIVATIVES IN THE PREVENTION OR TREATMENT OF TISSUE OR ORGAN TOXICITY INDUCED BY CYTOTOXIC AGENTS AND RADIATION”. The patent family provides granted patent protection in four countries, including the United States (U.S. Patent Number 8,765,726, expiry date: July 17, 2028), Japan (JP Patent Number 5213852, expiry date: September 25, 2026), and Germany (DE Patent Number 602006025897, expiry date: September 25, 2026). The granted claims relate to methods for using Hydronidone to treat certain cytotoxic- or radiation-induced injuries, such as pneumonitis.

The third patent family is entitled “METHOD FOR PREPARING HYDRONIDONE”. The patent family provides granted patent protection in Japan (JP Patent Number 6764998, expiry date: August 3, 2037) for a method of preparing Hydronidone.

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The fifth patent family is entitled “PHARMACEUTICAL HYDRONIDONE FORMULATIONS FOR DISEASES”. The patent family comprises a pending Patent Cooperation Treaty application (PCT/CN2021/088104, international filing date: April 19, 2021). The pending claims relate to methods for using Hydronidone to treat liver fibrosis, liver cirrhosis, advanced hepatitis B viral infection, or NASH fibrosis.

We expect to continue to file patent applications to cover methods of treating additional indications, as well as new forms, formulations, and methods of manufacturing Hydronidone.

Government Regulation

Government authorities in the United States, at the federal, state and local levels, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, product approval, manufacture, quality control, manufacturing changes, packaging, storage, recordkeeping, labeling, promotion, advertising, sales, distribution, marketing, and import and export of drugs and biologic products. Our current product candidates are expected to be regulated as drugs. The processes for obtaining regulatory approval in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities both pre- and post-commercialization, are a significant factor in the production and marketing of our products and our research and development activities and require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA and other government entities regulate drugs under the Federal Food, Drug, and Cosmetic Act (the “FDCA”) and the regulations promulgated thereunder, as well as other federal and state statutes and regulations. Failure to comply with applicable legal and regulatory requirements in the United States at any time during the product development process, approval process, or after approval, may subject us to a variety of administrative or judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, withdrawal of approvals, delay or suspension of clinical trials, issuance of warning letters and other types of regulatory letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil monetary penalties, refusals of or debarment from government contracts, exclusion from the federal healthcare programs, restitution, disgorgement of profits, civil or criminal investigations by the FDA, U.S. Department of Justice, State Attorneys General, and/or other agencies, False Claims Act suits and/or other litigation, and/or criminal prosecutions.

An applicant seeking approval to market and distribute a new drug in the United States must typically undertake the following:

- completion of pre-clinical laboratory tests, animal studies, and formulation studies in compliance with the FDA’s GLP, regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective without FDA objection before human clinical trials may begin;
- approval by an IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with the FDA’s good clinical practice (“GCP”), regulations, to establish the safety and effectiveness of the proposed drug product for each indication for which approval is sought;
- preparation and submission to the FDA of an NDA;

- review of the NDA by an FDA advisory committee, where applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the drug product, and the active pharmaceutical ingredient or ingredients thereof, are produced to assess compliance with cGMP, regulations and to assure that the facilities, methods, and controls are adequate to ensure the product's identity, strength, quality, and purity;
- payment of user fees, as applicable, and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, such as any REMS, or post-approval studies required by the FDA.

Preclinical Studies and an IND

Preclinical studies can include *in vitro* and animal studies to assess the potential for adverse events and, in some cases, to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. Other studies include laboratory evaluation of the purity, stability and physical form of the manufactured drug substance or API and the physical properties, stability and reproducibility of the formulated drug or drug product. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Some preclinical testing, such as longer-term toxicity testing, animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Following commencement of a clinical trial under an IND, the FDA may place a clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

Human Clinical Studies in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations.

Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

Phase 2: The product candidate is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites in late-stage clinical trials to assure compliance with GCP and the integrity of the clinical data submitted.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, currently $2.876 million for fiscal year 2021, for applications requiring clinical data, and the sponsor of an approved NDA is also subject to an annual program fee, currently $336,432 for fiscal year 2021. These fees are adjusted annually.

Under certain circumstances, the FDA will waive the application fee for the first human drug application that a small business, defined as a company with less than 500 employees, including employees of affiliates, submits for review. An affiliate is defined as a business entity that has a relationship with a second business entity if one business entity controls, or has the power to control, the other business entity, or a third-party controls, or has the power to control, both entities. In addition, an application to market a prescription drug product that has received orphan designation is not subject to a prescription drug user fee unless the application includes an indication for other than the rare disease or condition for which the drug was designated. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a disease or condition that affects fewer than 200,000 individuals in the United States, or for which there is no reasonable expectation that U.S. sales will be sufficient to recoup the development and production costs.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in

compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP.

The FDA also may require submission of a REMS plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information for the FDA to reconsider the application. If those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. After approval, the FDA may seek to prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. Some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track Designation, Accelerated Approval, Priority Review, Orphan Drug Designation and Breakthrough Therapy Programs

Fast Track

There are several FDA programs intended to help facilitate the development of new drugs and biologics that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biological product may request the FDA to designate the drug or biological product as a Fast Track product at any time during the clinical development of the product. Under a Fast Track designation, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the application.

Priority Review

A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review to facilitate the review.

Accelerated Approval

A product that is being studied for safety and effectiveness in treating serious or life-threatening illnesses and provides meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that it may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, for seven years. These circumstances are an inability to supply the drug in sufficient quantities or a situation in which a new formulation of the drug has shown superior safety or efficacy or a major contribution to patient care. This exclusivity, however, could also block the approval of its product for seven years if a competitor obtains earlier approval of the same drug for the same indication.

Rare Pediatric Drug Designation

There are FDA programs intended to help facilitate the development of new drugs and biologics that meet certain criteria. Specifically, new drugs and biological products are eligible for rare pediatric disease designation if they treat a serious or life-threatening condition that affects less than 200,000 individuals in the United States per year and who are primarily less than 18 years of age. Under the FDA's rare pediatric disease designation program, the FDA may grant a priority review voucher to a sponsor who receives a product approval for a rare pediatric disease.

Breakthrough Therapy Designation

A product may also be eligible for receipt of a Breakthrough Therapy designation. The Breakthrough Therapy designation is intended to expedite the FDA's review of a potential new drug for serious or life-threatening diseases where "preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." The designation of a drug as a Breakthrough Therapy provides the same benefits as are available under the Fast Track program, as well as intensive FDA guidance on the product's development program. Fast Track designation, priority review, accelerated approval and Breakthrough Therapy designation do not change the standards for approval, but they may expedite the development or approval process.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced

inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented.

FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events or problems with manufacturing processes of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant criminal and civil liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, (“PDMA”), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant’s product or a method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an Abbreviated New Drug Application (“ANDA”) applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

To the extent that a Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Legislative Developments

The 21st Century Cures Act (the "Cures Act"), which was signed into law in December 2016, includes provisions to accelerate the development and delivery of new treatments. For example, the Cures Act requires the FDA to establish a program to evaluate the potential use of real world evidence to help to support the approval of a new indication for an approved drug and to help to support or satisfy post-approval study requirements, to issue guidance on adaptive and novel clinical trial designs for new drugs, and to establish a process for qualifying drug development tools used to support FDA approval for marketing or investigational use of a drug. The Cures Act also permits the FDA to rely on qualified data summaries to support the approval of a supplemental application for an already approved drug. The FDA is in the process of implementing the Cures Act requirements.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, its activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to CMS, other divisions of the U.S. Department of Health and Human Services (*e.g.*, the Office of Inspector General), the U.S. Department of Justice, or DOJ and individual U.S. Attorney offices within the DOJ and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. There are statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that

may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Catalyst's practices may not in all cases meet all the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act ("ACA") to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the ACA codified case law 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 (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved and thus non-reimbursable, uses. HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Catalyst may be subject to data privacy and security regulations by both the federal government and the states in which Catalyst conducts its business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four 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, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the ACA and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

To distribute products commercially, Catalyst must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing and to prohibit certain other sales and marketing practices. All its activities are potentially subject to federal and state consumer protection and unfair competition laws.

If its operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to Catalyst, Catalyst may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow Catalyst to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of its operations, any of which could adversely affect its ability to operate its business and its results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which Catalyst obtains regulatory approval. In the United States and markets in other countries, sales of any products for which Catalyst receives regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, privately managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Catalyst may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of its products, in addition to the costs required to obtain the FDA approvals. Its product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. This is also true of Medicare reimbursement, where different vendors process payments, so that coverage by one vendor does not assure that all other vendors will provide coverage. Adequate third-party reimbursement may not be available to enable Catalyst to maintain price levels sufficient to realize an appropriate return on its investment in product development. In addition, the United States federal government position on matters related to drug pricing is evolving and uncertain and any changes could have a material impact on drug pricing generally in the United States, including for its product candidates if approved.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The National Institute for Health and Care Excellence (NICE) in the United Kingdom also requires consideration of cost-benefit analysis. The downward pressure on healthcare costs has become very intense. As a result, increasingly high barriers are being

erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which Catalyst receives regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and Catalyst expects will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which Catalyst receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect its business. These and other laws govern the use, handling and disposal of various biological, chemical and radioactive substances used in and wastes generated by, its operations. If its operations result in contamination of the environment or expose individuals to hazardous substances, Catalyst could be liable for damages and governmental fines. Catalyst believes that it is in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on its business. Catalyst cannot predict, however, how changes in these laws may affect its future operations.

Government Regulation Outside of the United States

In addition to regulations in the United States, Catalyst will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of its products. Whether or not Catalyst obtains FDA approval of a product, Catalyst must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, Catalyst must submit a marketing authorization application.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If Catalyst or its potential collaborators fail to comply with applicable foreign regulatory requirements, Catalyst may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees

We consider our ability to recruit, retain and motivate our employees to be critical to our success. We are an equal opportunity employer and we are fundamentally committed to creating and maintaining a work environment in which employees are treated with respect and dignity. All human resources policies, practices and actions related to hiring, promotion, compensation, benefits and termination are administered in accordance with the principal of equal employment opportunity, meaning that they are made on the basis of individual skills, knowledge, abilities, job performance and other legitimate criteria and without regard to race, color, religion, sex, sexual orientation, gender expression or identity, ethnicity, national origin, ancestry, age, mental or physical disability, genetic information, any veteran status, any military status or application for military service, or membership in any other category protected under applicable law.

As of December 31, 2022, we had 7 full-time employees. Of the full-time employees, as of such date, 1 employee was engaged in manufacturing and clinical development activities and 6 employees were engaged in finance, business development, facilities and general management. Of our employees as of December 31, 2022, 72% were male and 28% were female. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages. We consider our relations with our employees to be good.

We aim to provide our employees with competitive salary and benefits that enable them to achieve a good quality of life and plan for the future. Our benefits are based on local norms and market preferences, but include all salary and social benefits required by local law (including paid time off for vacation and sick leave) and many additional benefits that go beyond legal requirements.

To maintain and enhance the safety of our employees, we promote a culture of continuous improvement and individual accountability to provide safe workplaces. The safety of our employees has been a priority throughout our response to the COVID-19 pandemic. Our management team guided our operations in the processes and procedures to comply with applicable government-imposed health and safety-related operating restrictions, and to enhance the safety of our facilities to protect the health of our employees. The management team continues to operate, updating guidance as the pandemic has continued and the medical science and government guidance and orders have evolved. We continue to enforce COVID-19 health and safety protocols and have implemented protocols to address actual and suspected cases of COVID-19 and resulting contact tracing and quarantine requirements. Throughout the pandemic, we have been communicating regularly with our employees and monitoring their views on issues related to COVID-19 and the workplace as well as general levels of engagement. In addition, management has regularly updated our Board of Directors on our COVID-19 status and response, including with respect to employee safety.

Business Organization

We commenced operations in 2002 and are a Delaware corporation. On August 20, 2015, we merged with Targacept, Inc. Our corporate headquarters are in South San Francisco, California. We conduct our research and development activities and general and administrative functions primarily from our South San Francisco, California location.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports, are available for free at www.catalystbiosciences.com as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. They are also available for free on the SEC's website at www.sec.gov. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing.

Item 1A. RISK FACTORS

The following section includes the most significant factors that may adversely affect our business and operations. You should carefully consider the risks and uncertainties described below and all information contained in this Annual Report on Form 10-K before deciding to invest in our common stock. If any of the following risks actually occur, our business, financial condition, results of operations and growth prospects may be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose all or part of your investment.

Summary of Risk Factors

Investing in our securities involves a high degree of risk. Below please find a summary of the principal risks we face. These risks are discussed more fully below.

- *Catalyst's CVR was distributed to its stockholders of record on January 5, 2023; other stockholders, including purchasers of Catalyst common stock after January 5, 2023, will not benefit from the distribution under the CVR. CVR holders may potentially not receive any payment on the CVRs and the CVRs may otherwise expire valueless.*
- *During the pendency of the Transactions, Catalyst may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Business Combination Agreement, which could adversely affect its business prospects. Certain provisions of the Business Combination Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the transactions contemplated by the Business Combination Agreement.*
- *Catalyst may be subject to a new 1% U.S. federal excise tax in connection with the issuance of the CVRs.*
- *Catalyst may not be able to continue as a going concern if the conversion of Catalyst Convertible Preferred Stock is not approved by its stockholders.*
- *Catalyst has incurred significant losses since its inception and is expected to continue to incur significant losses for the foreseeable future.*
- *Catalyst will need additional capital to continue product development and may not be able to do so. If Catalyst is unable to raise sufficient capital, it will be forced to delay, reduce or eliminate product development programs.*
- *Catalyst has no history of obtaining regulatory approval or commercialization of pharmaceutical products, and it may be unable to do so for any product candidates Catalyst acquires or develops, including Hydronidone, which may make it difficult to evaluate Catalyst's prospects.*
- *Catalyst is substantially dependent on the success of its lead product candidate, Hydronidone, and its future clinical trials of Hydronidone may not be successful. Results from preclinical or early-stage clinical trials, including the results of preclinical testing and early clinical trials of Hydronidone, may not be confirmed in later trials or be predictive of the success of later clinical trials, including the results of Hydronidone's later clinical trials.*
- *If Catalyst experiences delays or difficulties in the commencement of clinical trials or patient enrollment in clinical trials, its regulatory approvals could be delayed or prevented.*
- *Catalyst may expend its limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.*
- *Catalyst's product candidates, including Hydronidone, may cause significant adverse events, toxicities or other undesirable side effects that may result in a safety profile that could prevent regulatory approval, marketing approval or market acceptance, or limit their commercial potential.*
- *Catalyst contracts with third parties for the manufacture of its product candidates for preclinical testing and expects to continue to do so for clinical testing and commercialization. This reliance on third parties increases the risk that Catalyst will not have sufficient quantities or quality of its product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair its development or commercialization efforts. Catalyst relies on third parties to conduct certain aspects of its preclinical studies*

and any clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such tasks or trials.

- *Catalyst's future success depends on its ability to retain key executives and to attract, retain and motivate qualified personnel.*
- *Catalyst's employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.*
- *Catalyst will continue to incur significant costs as a result of operating as a public company, and its management is required to devote substantial time to compliance initiatives. As a smaller reporting company ("SRC"), Catalyst cannot be certain if the SRC reduced disclosure requirements will make its common stock less attractive to investors.*
- *If Catalyst is unable to obtain, protect or enforce intellectual property rights related to its product candidates, Catalyst may not be able to compete effectively in its markets. Catalyst may also be involved in lawsuits to protect or enforce its patents.*
- *Catalyst's product candidates are years away from regulatory approval. The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If Catalyst is not able to obtain, or if there are delays in obtaining, required regulatory approvals, Catalyst will not be able to commercialize its product candidates, including Hydronidone, and its ability to generate revenue will be materially impaired.*
- *Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in Catalyst's failing to obtain regulatory approval to market Catalyst's product candidates, including Hydronidone, which would significantly harm Catalyst's business, results of operations and prospects.*
- *Catalyst is developing Hydronidone for the treatment of NASH, an indication for which there are no approved products. The requirements for approval of Hydronidone by the FDA and comparable foreign regulatory authorities may be difficult to predict and may change over time, which makes it difficult to predict the timing and costs of the clinical development.*
- *Catalyst's relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose Catalyst to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.*
- *Catalyst's results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions. Fluctuations in operating results could adversely affect the price of Catalyst's common stock.*
- *Catalyst is subject to evolving privacy and data protection laws, including HIPAA and the EU General Data Protection Regulation (EU) 2016/679 ("GDPR"). If Catalyst fails to protect personal information or comply with existing or future data protection regulations, its business, financial condition, results of operations and prospects may be materially adversely affected.*
- *Catalyst identified a material weakness in its internal control over financial reporting in its consolidated financial statements for the year ended December 31, 2021. If Catalyst fails to maintain effective internal control over financial reporting, Catalyst may not be able to accurately or timely report its financial condition or results of operations, which may adversely affect its business and share price.*
- *The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit its ability to market those products and decrease its ability to generate revenue.*

- *The market price of Catalyst Common Stock has historically been highly volatile. Sales of a significant number of shares of Catalyst's common stock in the public markets, or the perception that such sales could occur, could depress the market price of its common stock.*
- *Anti-takeover provisions in its charter documents and provisions of Delaware law may make an acquisition more difficult and could result in the entrenchment of management.*
- *Catalyst has recently received a Nasdaq notice for failing to comply with the minimum bid price listing requirement and there is no assurance Catalyst will regain compliance or maintain its Nasdaq listing.*

Risks Related to the Strategic Transactions

Risks Related to the Business Combination Transactions

Catalyst's CVR was distributed to its stockholders of record on January 5, 2023; other stockholders, including purchasers of Catalyst common stock after January 5, 2023, will not benefit from the distribution under the CVR. CVR holders may potentially not receive any payment on the CVRs and the CVRs may otherwise expire valueless.

Pursuant to the Contingent Value Rights Agreement (the "CVR Agreement") dated December 26, 2022, Catalyst's CVR was distributed to its stockholders of record on January 5, 2023. CVR distributions, if any, will consist of net proceeds from any potential future sale of Catalyst's legacy assets or claims, net cash in excess of $1.0 million, as of the closing of the Transactions, net cash received from the transaction with Vertex in May 2022, up to $5.0 million, net proceeds from the payment of the remaining $5.0 million due from the sale of Catalyst's legacy hemophilia assets to GCBP, and net proceeds from certain legal claims that Catalyst has against a third party. The amount that can be distributed will depend on a variety of factors, including the value, if any, received for Catalyst's legacy assets or claims, the amount of expenses Catalyst incurs before the closing of the Transactions, and the amount, if any, received from Vertex and GCBP. There can be no assurance as to the timing or amount of distributions to Catalyst's stockholders pursuant to the CVR Agreement, and such amounts may ultimately be higher or lower than anticipated.

Furthermore, other Catalyst stockholders, including purchasers of Catalyst common stock after January 5, 2023, will not benefit from the distribution under the CVR.

Catalyst may not be able to achieve successful results from the disposition of such assets as described above. If this is not achieved for any reason within the time periods specified in the CVR Agreement, or the permitted deductions set forth in the CVR Agreement are greater than any gross proceeds, no payments will be made under the CVRs, and the CVRs will expire valueless.

During the pendency of the Transactions, Catalyst may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Business Combination Agreement, which could adversely affect its business prospects.

Covenants in the Business Combination Agreement impede the ability of Catalyst to make acquisitions during the pendency of the Transactions, subject to specified exceptions. In addition, while the Business Combination Agreement is in effect, Catalyst is generally prohibited from soliciting, proposing, seeking or knowingly encouraging, facilitating or supporting any inquiries, indications of interest, proposals or offers that constitute or may reasonably be expected to lead to certain transactions involving a third party, including a merger, sale of assets or other business combination, subject to specified exceptions. Any such transactions could be favorable to Catalyst's stockholders, but Catalyst may be unable to pursue them. In addition, if the Business Combination Agreement is terminated under specified circumstances, Catalyst would be required to pay the Contributors a termination fee of $2.0 million and reimburse the Contributors for all of their reasonable out-of-pocket fees and expenses up to $2.0 million. This termination fee and expense reimbursement may discourage third parties from submitting competing proposals to Catalyst or its stockholders, and may cause the Catalyst Board of Directors to be less inclined to recommend a competing proposal.

Certain provisions of the Business Combination Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the transactions contemplated by the Business Combination Agreement.

The terms of the Business Combination Agreement prohibit Catalyst from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances. In addition, if the Business Combination Agreement is terminated under specified circumstances, Catalyst would be required to pay the Contributors a termination fee of $2.0 million and reimburse the Contributors for all of their reasonable out-of-pocket fees and expenses up to $2.0 million. This termination fee and expense reimbursement may discourage third parties from submitting competing proposals to Catalyst or its stockholders, and may cause the Catalyst board of directors to be less inclined to recommend a competing proposal.

Because the lack of a public market for BC's common shares makes it difficult to evaluate the fair market value of BC's common shares, Catalyst may pay more than the fair market value of the indirect controlling interest in BC and/or GNI USA and the Minority Holders may receive consideration in the Transactions that is less than the fair market value of their indirect ownership of BC.

The outstanding common shares of BC are privately held and are not traded in any public market. The lack of a public market makes it difficult to determine the fair market value of BC's common shares. Because the percentage of Catalyst equity to be issued to GNI USA and the Minority Holders was determined based on negotiations between the parties, it is possible that the value of the Catalyst Common Stock to be received by GNI USA and the Minority Holders will be less than the fair market value of their indirect ownership of BC, or Catalyst may pay more than the aggregate fair market value for the indirect controlling interest in BC.

The U.S. federal income tax treatment of the CVRs is unclear, and there can be no assurance that the Internal Revenue Service would not assert, or that a court would not sustain, a position that could result in adverse U.S. federal income tax consequences to holders of the CVRs.

The U.S. federal income tax treatment of the CVRs is unclear. There is no legal authority directly addressing the U.S. federal income tax treatment of the receipt of, and payments on, the CVRs, and there can be no assurance that the IRS would not assert, or that a court would not sustain, a position that could result in adverse U.S. federal income tax consequences to holders of the CVRs. Catalyst will treat the issuance of the CVRs as a distribution of property with respect to its stock. However, there is no authority directly addressing whether contingent value rights with characteristics similar to the CVRs should be treated as a distribution of property with respect to the corporation's stock, a distribution of equity, a "debt instrument" or an "open transaction" for U.S. federal income tax purposes. In addition, although Catalyst will estimate the value of the CVRs for purposes of reporting the distribution on Form 1099 to Catalyst stockholders, the value of the CVRs is uncertain, and the IRS or a court could determine that the value of the CVRs at the time of issuance was higher. In such case, the Catalyst stockholders could be treated as having additional income or gain upon receipt of the CVRs. Further, notwithstanding Catalyst's position that the receipt of CVRs and the proposed reverse stock split are appropriately treated as separate transactions, it is possible that the IRS or a court could determine that the Catalyst stockholders' receipt of the CVRs and the proposed reverse stock split constitute a single "recapitalization" for U.S. federal income tax purposes. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to Catalyst's position, which could result in adverse U.S. federal income tax consequences to holders of the CVRs.

Catalyst may be subject to a new 1% U.S. federal excise tax in connection with the issuance of the CVRs.

On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 ("IRA"), which, among other things, imposes a 1% excise tax (the "Excise Tax") on certain repurchases of stock by publicly-traded domestic corporations. The Excise Tax will apply to repurchases occurring in 2023 and beyond. The amount of the Excise Tax is generally 1% of the fair market value of the repurchased stock at the time of the repurchase. The U.S. Department of the Treasury has authority to provide regulations and other guidance to carry out, and prevent the abuse or avoidance of, the Excise Tax. On December 27, 2022, the U.S. Department of the Treasury issued Notice 2023-2, which provides interim guidance regarding the application of the Excise Tax pending forthcoming proposed regulations. Catalyst is in the process of performing analysis of the Company's earnings and profits which could result in the treatment of some or all of the distribution to be treated as a dividend for U.S. federal income tax purposes. Any portion of the issuance of CVRs that is not treated as a dividend may be subject to the 1% Excise Tax under the IRA.

The extent of the Excise Tax that Catalyst may incur would depend on a number of factors, including the extent such issuances could be treated as dividends and not repurchases, fair market value of the Catalyst Common Stock treated as being redeemed (if any), and the content of any regulations and other guidance from the U.S. Department of the Treasury that may be issued and applicable to such issuances. In addition, the amount of Excise Tax imposed with respect to repurchases of stock by a repurchasing corporation may be reduced by the fair market value of stock issued by the repurchasing corporation during the same taxable year. Absent the issuance of applicable guidance to the contrary, Catalyst currently expects that this reduction may be available with respect to the issuance of the Catalyst Common Stock in the Contributions. It is possible, however, that applicable guidance is issued that would prevent or limit the potential application of this rule.

The Excise Tax is imposed on the repurchasing corporation itself, not the investors from which shares are repurchased, and the mechanics of any required payment of the Excise Tax have not yet been determined. The imposition of the Excise Tax, if any, with respect to the issuance of the CVRs could reduce the amount of cash available to Catalyst and have a material adverse effect on liquidity and operations.

Catalyst may not be able to continue as a going concern if the conversion of Catalyst Convertible Preferred Stock is not approved by its stockholders.

As part of the F351 Agreement, Catalyst issued 12,340 shares of Catalyst Convertible Preferred Stock, which upon stockholder approval, will be converted to Catalyst Common Stock, subject to applicable beneficial ownership limitations. The terms of the Catalyst Convertible Preferred Stock include a cash settlement feature which provides that if Catalyst stockholders fail to approve the conversion of the Catalyst Convertible Preferred Stock by September 30, 2023, Catalyst could be required to make cash payments to the holders of Catalyst Convertible Preferred Stock significantly in excess of its current liquidity. Catalyst believes that stockholders who are entitled to vote on the conversion proposal at Catalyst's 2023 Annual Meeting of Stockholders, which is expected to be held in the third quarter of 2023, will vote to approve the proposal. However, the vote of the Company's common stockholders is outside of Catalyst's control. Our independent registered public accounting firm has issued a report that raised substantial doubt about Catalyst's ability to continue as a going concern.

Risks Related to Catalyst

As described below, if the Transactions are not completed, Catalyst will reconsider its strategic alternatives, including dissolving and liquidating its assets, pursuing another strategic transaction, or operating its business. If the Transactions are not completed, Catalyst will face various risks related to its financial condition and need for capital; its ability to execute on alternative strategies; discovery, development and commercialization of its product candidates; its intellectual property; regulatory and compliance matters; and its status as a public company, all as further discussed in the Risk Factors, including this subsection titled "—Risks Related to Catalyst."

Risks Related to Catalyst's Financial Condition and Capital Requirements

Catalyst has incurred significant losses since its inception and is expected to continue to incur significant losses for the foreseeable future.

Catalyst is a preclinical-stage biotechnology company and has not yet generated significant revenues. Catalyst has incurred net losses in each year since its inception in August 2002, including net losses of $8.2 million and $87.9 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, Catalyst had an accumulated deficit of $410.9 million.

Even after the acquisition of the F351 Assets, Catalyst is still in the early stages of development of its product candidates, and has no products approved for commercial sale. To date, Catalyst has financed its operations primarily through issuances of shares of common stock, from private placements of convertible preferred stock, and from payments under collaboration agreements.

Catalyst has devoted most of its financial resources to research and development, including its preclinical and clinical development activities. If the Transactions are not consummated, Catalyst expects to continue to incur significant expenses and operating losses over the next several years as it continues the development of its complement product candidates. Catalyst's operating losses may fluctuate significantly from quarter to quarter and year to year. Catalyst is expected to continue to incur significant expenses and operating losses for at least the next several years as it:

- continues clinical development of Hydronidone;
- further develops the manufacturing process for its product candidates;
- attracts, hires and retains skilled personnel;
- seeks regulatory and marketing approvals for any of its product candidates that successfully complete clinical studies;
- acquires or in-licenses other product candidates and technologies;
- maintains, protects and expands its intellectual property portfolio;
- creates additional infrastructure to support operations as a public company and its product development and planned future commercialization efforts; and
- experiences any delays or other issues with any of the above.

To become and remain profitable, Catalyst must succeed in developing and eventually commercializing products that generate significant revenue. This will require Catalyst to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which regulatory approval is obtained. Catalyst is only in the preliminary stages of most of these activities. Catalyst may never succeed in these activities and, even if it does, it may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, Catalyst is unable to accurately predict the timing or amount of increased expenses or when, or if, Catalyst will be able to achieve profitability. Even if Catalyst does achieve profitability, Catalyst may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable would depress the value of Catalyst's common stock and could impair Catalyst's ability to raise capital, expand its business, maintain research and development efforts, diversify product offerings or even continue operations. A decline in the value of Catalyst's common stock could also cause you to lose all or part of your investment.

If the Transactions are not completed, Catalyst will reconsider its strategic alternatives, including dissolving and liquidating its assets, pursuing another strategic transaction, or operating its business. Catalyst's future capital requirements depend on many factors, and adequate additional financing may not be available to it on acceptable terms, or at all.

Catalyst expects to devote significant time and resources to the completion of the Transactions. However, there can be no assurances that such activities will result in the completion of the Transactions. If the Transactions are not completed, Catalyst will reconsider its strategic alternatives. Catalyst considers one of the following courses of action to be the most likely alternatives if the Transactions are not completed:

Dissolve and liquidate its assets. If, for any reason, the Transactions do not close, Catalyst's board of directors may conclude that it is in the best interest of stockholders to dissolve the Company and liquidate its assets. In that event, Catalyst would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims. There would be no assurances as to the amount or timing of available cash remaining to distribute to stockholders after paying Catalyst's obligations and setting aside funds for reserves.

Pursue another strategic transaction. Catalyst may resume the process of evaluating a potential strategic transaction in order to attempt another strategic transaction like the Transactions.

Operate its business. Catalyst's board of directors may elect to seek new product candidates for development.

Raise additional capital. Catalyst may raise additional capital to fund its development of Hydronidone, which may be dilutive to Catalyst stockholders. For details regarding the risks related to raising additional capital, see the Risk Factor entitled "*—Catalyst will need additional capital to continue product development and may not be able to do so. If Catalyst is unable to raise sufficient capital, it will be forced to delay, reduce or eliminate product development programs.*"

If Catalyst's board of directors elects to seek new product candidates for development, Catalyst expects that it would incur significant research and development expenses. If Catalyst is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate any such future research and development programs or commercialization efforts and/or Catalyst could be forced to revise or abandon its current business strategy.

Catalyst will need additional capital to continue product development and may not be able to do so. If Catalyst is unable to raise sufficient capital, it will be forced to delay, reduce or eliminate product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. If Catalyst continues with preclinical and clinical development activities, it will continue to incur expenses related to the preclinical and clinical development of its complement product candidates. Catalyst believes that its available cash and cash equivalents will be sufficient to fund its operations for at least the next 12 months assuming Catalyst's stockholders approve the conversion of Catalyst Convertible Preferred Stock. However, Catalyst expects to need to raise substantial additional capital to continue the clinical development of Hydronidone and depending on the availability of capital, may need to delay or cease development of some or all of its product candidates. Even if Catalyst raises additional capital, it may elect to focus its efforts on one or more development programs and delay or cease other development programs.

Until Catalyst can generate sufficient revenue from its product candidates, if ever, it expects to finance future cash needs through public or private equity offerings, debt financings, corporate collaborations and/or licensing arrangements. Additional funds may not be available when Catalyst needs them on terms that are acceptable, or at all. If adequate funds are not available, Catalyst may be required to delay, reduce the scope of or eliminate some or all of its research or development programs.

Because successful development of its product candidates is uncertain, Catalyst is unable to estimate the actual funds required to complete research and development and commercialize its products under development. Catalyst's future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the costs and results of preclinical studies or clinical trials of Hydronidone or its other complement product candidates, and expenses related to potential clinical development of such candidates;
- the number and characteristics of product candidates that it pursues;
- the costs it incurs related to the sale of its legacy assets or claims;
- the terms and timing of any future collaboration, licensing or other arrangements that Catalyst may establish;
- its headcount and costs associated with hiring or retaining personnel;
- the outcome, timing and cost of regulatory approvals;
- the cost of obtaining, maintaining, defending and enforcing intellectual property rights, including patent rights;
- the effect of competing technological and market developments;
- the cost and timing of completing outsourced manufacturing activities;
- market acceptance of any product candidates for which Catalyst may receive regulatory approval;

- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which Catalyst may receive regulatory approval;
- the costs of continuing to operate its business, including costs associated with being a public company; and
- the extent to which Catalyst acquires, licenses or invests in businesses, products or technologies.

If the Transactions are not consummated, Catalyst will require additional capital to achieve its business objectives. Additional funds may not be available on a timely basis, on favorable terms or at all, and such funds, if raised, may not be sufficient to enable it to continue to implement Catalyst's long-term business strategy. Any additional fundraising efforts may divert its management from their day-to-day activities, which may adversely affect its ability to develop and commercialize its product candidates. Further, its ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic or the conflict between Russia and Ukraine. If Catalyst is unable to raise sufficient additional capital, it could be forced to curtail its planned operations and the pursuit of its strategy.

As discussed above, if the Transactions are not completed, Catalyst will reconsider its strategic alternatives, including dissolving and liquidating its assets, pursuing another strategic transaction, or operating its business. If Catalyst's board of directors elects to seek product candidates for development, Catalyst will face the risks related to discovery, development and commercialization of its product candidates set forth in this section, in addition to other risks described in this Risk Factors section.

Raising additional funds by issuing securities or through licensing arrangements may cause dilution to stockholders, restrict Catalyst's operations or require Catalyst to relinquish proprietary rights.

To the extent that Catalyst raises additional capital through the sale of equity or convertible debt securities, stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Catalyst currently has in place an Equity Distribution Agreement with Piper Sandler & Co. that permits it, subject to applicable SEC regulations, to issue up to $50.0 million worth of shares of its common stock in "at the market" transactions at prevailing market prices.

Debt financing, if available at all, may involve agreements that include covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If Catalyst raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, Catalyst may have to relinquish valuable rights to its technologies, product candidates or future revenue streams or grant licenses on terms that are not favorable to Catalyst. Catalyst may also seek to access the public or private capital markets whenever conditions are favorable, even if it does not have an immediate need for additional capital at that time. There can be no assurance that Catalyst will be able to obtain additional funding if, and when necessary. If Catalyst is unable to obtain adequate financing on a timely basis, Catalyst could be required to delay, curtail or eliminate one or more, or all, of its development programs or grant rights to develop and market product candidates that Catalyst would otherwise prefer to develop and market ourselves.

Catalyst currently has an effective registration statement on Form S-3 that allows Catalyst to offer up to $150.0 million of securities in one or more offerings, subject to limitations under applicable SEC rules, including up to $50.0 million of common stock issuable under its Equity Distribution Agreement with Piper Sandler & Co. Any additional sales in the public market of its common stock or other securities under these shelf registration statements could adversely affect prevailing market prices for its common stock.

Risks Related to Catalyst's Business Operations and Product Candidates

Catalyst has no history of obtaining regulatory approval or commercialization of pharmaceutical products, and it may be unable to do so for any product candidates Catalyst acquires or develops, including F351, which may make it difficult to evaluate Catalyst's prospects.

Catalyst began operations in August 2002. Catalyst's operations to date have been limited to financing and staffing the Company, developing its technology and product candidates, establishing collaborations and conducting phase 2 clinical trials on small numbers of patients. Catalyst has not yet demonstrated an ability to successfully conduct a phase 3 clinical trial, obtain marketing approvals, manufacture a product at commercial scale repeatedly, or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about Catalyst's future product development timelines, clinical trial plans, expenses, success or viability may not be as accurate as they could be if Catalyst had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

If Catalyst is required to conduct additional preclinical studies or clinical trials of Hydronidone beyond those that Catalyst currently contemplates, if Catalyst is unable to successfully complete clinical trials of Hydronidone or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, Catalyst may:

- be delayed in obtaining regulatory approval from the FDA, EMA or other regulatory authorities for Hydronidone;
- not obtain regulatory approval at all and lose its ability to further develop and commercialize Hydronidone;
- obtain regulatory approval for indications or patient populations that are not as broad as intended or desired;
- continue to be subject to post-marketing testing requirements from the FDA, EMA or other regulatory authorities; or
- experience having the product removed from the market after obtaining regulatory approval.

Catalyst is substantially dependent on the success of its lead product candidate, Hydronidone, and its future clinical trials of Hydronidone may not be successful.

Catalyst's future success is substantially dependent on its ability to timely obtain marketing approval for, and then successfully commercialize, Hydronidone, Catalyst's lead product candidate. Catalyst expects to invest a majority of its efforts and financial resources into the research and development of Hydronidone. Catalyst is planning to initiate a Phase 2a, Proof-of-Concept ("PoC") clinical trial in late 2023 to evaluate the safety, tolerability, PK, and PD of Hydronidone for patients with advanced liver fibrosis associated with noncirrhotic NASH. The FDA has provided pre-IND advice on the design of the planned Phase 2a trial of Hydronidone and provided clear guidance on the requirements for the IND filing. If Catalyst observes positive trends in the Phase 2a trial of Hydronidone, it expects to initiate a Phase 2 trial of Hydronidone.

Hydronidone will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before Catalyst generates any revenues from product sales. Catalyst is not permitted to market or promote Hydronidone, or any other product candidates, before Catalyst receives marketing approval from the FDA and comparable foreign regulatory authorities, and Catalyst may never receive such marketing approvals.

The success of Hydronidone will depend on a variety of factors. Catalyst does not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to Catalyst's intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, Catalyst cannot assure you that it will ever be able to generate revenue through the sale of Hydronidone, even if approved. If Catalyst is not successful in commercializing Hydronidone, or is significantly delayed in doing so, Catalyst's business will be materially harmed.

If Catalyst experiences delays or difficulties in the commencement of clinical trials or patient enrollment in clinical trials, its regulatory approvals could be delayed or prevented.

Catalyst or its collaborators may not be able to initiate or continue clinical trials for its product candidates if Catalyst is unable to locate, enroll and maintain enrollment of a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Furthermore, there are inherent difficulties in enrolling NASH patients, which can currently only be definitively diagnosed through a liver biopsy. Specifically, identifying patients most likely to meet NASH enrollment criteria on biopsy is an on-going challenge, with existing clinical indicators lacking both sensitivity and specificity. As a result, NASH trials often suffer from high levels of screen failure following central review of the baseline liver biopsy, which can lead to lower enrollment. As a result of such difficulties and the significant competition for recruiting NASH patients in clinical trials, Catalyst or its future collaborators may be unable to enroll the patients Catalyst needs to complete clinical trials on a timely basis, or at all. In addition, Catalyst's competitors, some of whom have significantly greater resources than Catalyst does, are conducting clinical trials for the same indications and seek to enroll patients in their studies that may otherwise be eligible for Catalyst's clinical studies or trials. Since the number of qualified clinical investigators is limited, Catalyst expects to conduct some of its clinical trials at the same clinical trial sites that some of Catalyst's competitors use, which could further reduce the number of patients who are available for Catalyst's clinical trials in these sites. The availability of other approved products and other products in clinical trials have and may limit the number of patients willing to participate in Catalyst's clinical trials.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- clinical trials of other product candidates in the same indication;
- laboratory testing and turnaround time for samples needed for eligibility assessments;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Catalyst's inability to enroll a sufficient number of patients for its clinical trials will result in significant delays and could require Catalyst to abandon one or more clinical trials altogether. Enrollment delays in clinical trials conducted by Catalyst may also result in increased development costs for its product candidates, which would cause the value of Catalyst to decline and limit its ability to obtain additional financing.

Geopolitical events and global economic conditions, public health crises such as COVID-19, and the conflict between Russia and Ukraine may impact Catalyst's third-party supply of the raw materials and components needed for its product candidates, which increases the risk that Catalyst will not have sufficient quantities of such product candidates or products or such quantities at an acceptable cost, which delay, prevent or impair its development efforts.

If supplies of the raw materials for its product candidates are significantly delayed, or if the third parties that Catalyst engages to supply any materials or to manufacture any products for its preclinical tests and clinical trials should cease to continue to do so for any reason, including due to the effects of global economic conditions, including inflation and rising interest rates, public health crises such as the COVID-19 pandemic, and the conflict between Russia and Ukraine, Catalyst likely would experience delays in advancing these tests and trials while Catalyst identifies and qualifies replacement suppliers or manufacturers and Catalyst may be unable to obtain replacement supplies on terms that are favorable to Catalyst. In addition, if Catalyst is not able to obtain adequate supplies of its product candidates or the substances used to manufacture them, it will be more difficult for Catalyst to develop its product candidates and compete effectively.

Catalyst's current and anticipated dependence upon third-party suppliers may adversely affect its ability to develop product candidates and could delay its clinical trials and development programs, and otherwise harm its operations and financial condition and increase its costs and expenses.

Risks Related to the Discovery, Development and Commercialization of Catalyst's Product Candidates

Catalyst may expend its limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because Catalyst has limited financial and management resources, Catalyst must focus on development programs and product candidates that Catalyst identifies for specific indications. As such, Catalyst is currently primarily focused on the development of Hydronidone. As a result, Catalyst may forego or delay pursuit of opportunities with other product candidates or for other indications for these product candidates that later prove to have greater commercial potential. Catalyst's resource allocation decisions may cause Catalyst to fail to capitalize on viable commercial products or profitable market opportunities. Catalyst's spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If Catalyst does not accurately evaluate the commercial potential or target market for a particular product candidate, Catalyst may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for Catalyst to retain sole development and commercialization rights to such product candidate.

Catalyst may not be successful in its efforts to build a pipeline of additional product candidates.

Catalyst may not be able to continue to identify and develop new product candidates in addition to its current pipeline. Even if Catalyst is successful in continuing to build its pipeline, the potential product candidates that Catalyst identifies may not be suitable for clinical development. For example, product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be successfully developed, much less receive marketing approval and achieve market acceptance. If Catalyst does not successfully develop and commercialize product candidates based upon its approach, Catalyst will not be able to obtain product revenue in future periods, which likely would result in significant harm to its financial position and adversely affect its stock price. Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Results from preclinical or early-stage clinical trials, including the results of BC's preclinical testing and early clinical trials of Hydronidone, may not be confirmed in later trials or be predictive of the success of later clinical trials, including the results of Hydronidone's later clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of late-stage clinical trials. Trials of Catalyst's product candidates in larger numbers of patients may not have similar efficacy results and could result in adverse effects that were not observed in the earlier trials with smaller numbers of patients.

Catalyst will be required to demonstrate substantial evidence through well-controlled clinical trials that Catalyst's Hydronidone is safe and effective before Catalyst can seek marketing approvals for Hydronidone's commercial sale. Demonstrations of efficacy or an acceptable safety profile in BC's prior preclinical studies does not mean that future clinical trials will yield the same results. For instance, Catalyst does not know whether Hydronidone will perform in future clinical trials as Hydronidone has performed in preclinical studies and early clinical trials conducted by BC, and, despite Hydronidone's phase 1 trial in the United States demonstrating a favorable safety profile, tolerability and PK and BC's phase 2 clinical trial in the PRC demonstrating promising efficacy results in the reversal of HBV-associated fibrosis, to date, there is no effective clinical therapy for liver fibrosis, and no specific therapeutic drugs have been approved worldwide. Product candidates, including Hydronidone, may fail to demonstrate in later-stage clinical trials sufficient safety and efficacy to the satisfaction of the FDA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and earlier stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until Catalyst has demonstrated satisfactory safety or efficacy results in earlier-stage trials. In particular, in late 2023, we plan to initiate a Phase 2a PoC clinical trial to evaluate the safety, tolerability, PK, and initial efficacy of Hydronidone in patients with advanced liver fibrosis associated with noncirrhotic NASH. The FDA has reviewed the planned Phase 2a trial of Hydronidone and provided clear guidance on the design and trial assessment as well as requirements for the IND filing. If Catalyst observes positive trends in the Phase 2a trial of Hydronidone, it expects to initiate a larger Phase 2 trial in Hydronidone. Although data from liver

fibrosis associated with chronic hepatitis B ("CHB") patients in BC's phase 2 clinical trial in the PRC demonstrated Hydronidone has the potential to improve liver fibrosis, the efficacy of the Hydronidone in prior preclinical studies in a NASH model does not mean that future clinical trials will yield the same results. There is no guarantee that the FDA and other comparable foreign regulatory authorities will consider the data obtained in the Phase 2 trial sufficient to allow Catalyst to expand the development of Hydronidone in a larger Phase 2 or confirmatory Phase 3 clinical trial. Even if Catalyst is able to initiate Catalyst's planned clinical trials on schedule, there is no guarantee that Catalyst will be able to complete such trials on the timelines Catalyst anticipates or that such trials will produce positive results. Any limitation on Catalyst's ability to conduct clinical trials could delay or prevent regulatory approval or limit the size of the patient population to which Catalyst may market Catalyst's product candidates, if approved.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage NASH clinical trials after achieving positive results in earlier development, and Catalyst may face similar setbacks. The likelihood of obtaining regulatory approval can only be determined from data obtained in clinical trials and the totality of evidence on the efficacy and safety of a product. Many companies that believed their product candidates performed satisfactorily in preclinical studies and early clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if Catalyst believes that the results of clinical trials for its product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of its product candidates without conducting additional studies.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Any phase 2, phase 3 or other clinical trials that Catalyst may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market its product candidates.

Preliminary, "top-line" or interim data from Catalyst's clinical trials that it announces or publishes from time to time may change as more patient data become available and are subject to audit and verification procedures.

From time to time, Catalyst may publicly disclose preliminary or top-line data from its clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. Catalyst also makes assumptions, estimations, calculations and conclusions as part of its analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or top-line results that Catalyst reports may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures.

Any preliminary or top-line data should be viewed with caution until the final data are available. From time to time, Catalyst may also disclose interim data from Catalyst's preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from Catalyst's clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with Catalyst's assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and Catalyst's company in general. In addition, the information Catalyst chooses to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what Catalyst determines is material or otherwise appropriate information to include in Catalyst's disclosure. If the preliminary, top-line or interim data that Catalyst reports differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, Catalyst's ability to obtain approval for, and commercialize, Catalyst's product candidates may be harmed, which could harm Catalyst's business, operating results, prospects or financial condition.

A variety of risks associated with marketing Catalyst's product candidates internationally may materially adversely affect Catalyst's business.

Catalyst may also plan to eventually seek regulatory approval of Catalyst's Hydronidone outside of the United States and, accordingly, Catalyst expects that it will be subject to additional risks related to operating in foreign countries if Catalyst obtains the necessary approvals, including differing regulatory requirements in foreign countries. Risks associated with international operations may materially adversely affect Catalyst's business, financial condition and results of operations.

Catalyst's product candidates, including Hydronidone, may cause significant adverse events, toxicities or other undesirable side effects that may result in a safety profile that could prevent regulatory approval, marketing approval or market acceptance, or limit their commercial potential.

If Catalyst's product candidates, including Hydronidone, are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or INDs, Catalyst may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may prevent Catalyst from achieving or maintaining market acceptance of the affected product candidate and may adversely affect Catalyst's business, financial condition and prospects significantly.

In general, the anticipated clinical trials of Hydronidone will include patients with advanced liver fibrosis who are at risk of further progression to cirrhosis and deterioration, but are not critically ill. A certain percentage of patients with HBV-induced liver fibrosis treated with Hydronidone have experienced adverse events, including gastrointestinal diseases, ear and labyrinth diseases, systemic diseases, metabolic and nutritional diseases, skin and subcutaneous tissue diseases, heart organ diseases, and hepatobiliary system diseases. However, the risk/benefit of Hydronidone in NASH may differ from that shown in HBV liver fibrosis patients and there is always a risk that the severity and frequency of the adverse events may worsen. See the section titled "Business – Hydronidone Overview."

Adverse events or deaths in clinical trials involving Catalyst's product candidates, even if not ultimately attributable to Catalyst's product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of Catalyst's product candidates, stricter labeling requirements for those product candidates that are licensed and a decrease in demand for any such product candidates.

Additionally, if one or more of Catalyst's product candidates receives marketing approval and Catalyst or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result. For example, regulatory authorities may suspend, limit or withdraw approvals of such product or seek an injunction against its manufacture or distribution, require additional warnings on the label, including "boxed" warnings, or issue safety alerts, require press releases or other communications containing warnings or other safety information about the product, require Catalyst to change the way the product is administered or conduct additional clinical trials or post-approval studies, require Catalyst to create a risk evaluation and mitigation strategy ("REMS") which could include a medication guide outlining the risks of such side effects for distribution to patients, impose fines, injunctions or criminal penalties. Catalyst could also be sued and held liable for harm caused to patients, and Catalyst's reputation may suffer. Any of these events could prevent Catalyst from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm Catalyst's business.

Breakthrough Therapy designation by the FDA for any product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that the product candidate will receive marketing approval.

Hydronidone was recently designated as a Breakthrough Therapy in the PRC and is currently conducting a Phase 3 clinical trial for regulatory approval by the National Medical Products Administration ("NMPA") in the PRC. Catalyst may, in the future, apply for Breakthrough Therapy designation in the United States, or the equivalent thereof in other foreign jurisdictions (where available), for its product candidates, depending on robustness of the clinical benefit in clinical trials. A Breakthrough Therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the New Drug Applications ("NDA").

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if Catalyst believes that one of its product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of its product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

Risks Related to Catalyst's Reliance on Third Parties

Catalyst expects to seek to establish additional collaborations, and, if Catalyst is not able to establish them on commercially reasonable terms, Catalyst may have to alter its development and commercialization plans.

Catalyst's drug development programs and the potential commercialization of its product candidates will require substantial additional cash to fund expenses. Catalyst has previously relied on collaborators, such as Biogen, Pfizer and ISU, to contribute to the development of its product candidates. Catalyst may, in the future, form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that it believes will complement or augment Catalyst's development and commercialization efforts with respect to Hydronidone and/or Catalyst more broadly. Any of these relationships may require Catalyst to increase its near and long-term expenditures, issue securities that dilute Catalyst's existing stockholders or disrupt its management and business.

Catalyst faces significant competition in seeking appropriate collaborators. Whether Catalyst can reach a definitive agreement with a collaborator will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of preclinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with Catalyst. There can also be no assurance that Catalyst will enter into any collaboration agreements, or that any such agreements will be on favorable terms.

Collaborations are complex and time consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Catalyst may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If Catalyst is unable to do so, Catalyst may have to curtail the development of the product candidate for which Catalyst is seeking to collaborate, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of any sales or marketing

activities, and increase its expenditures and undertake development or commercialization activities at its own expense. If Catalyst elects to increase its expenditures to fund development or commercialization activities on its own, Catalyst may need to obtain additional capital, which may not be available to Catalyst on acceptable terms or at all. If Catalyst does not have sufficient funds, Catalyst may not be able to further develop its product candidates or bring them to market and generate product revenue.

Catalyst contracts with third parties for the manufacture of its product candidates for preclinical testing and expects to continue to do so for clinical testing and commercialization. This reliance on third parties increases the risk that Catalyst will not have sufficient quantities or quality of its product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair its development or commercialization efforts.

Catalyst currently has no internal capabilities to manufacture its product candidates for clinical use or for preclinical trials following good manufacturing practices ("GMP"), or good laboratory practices ("GLP"). Catalyst expects to rely on one or more third-party contractors to manufacture, package, label and distribute clinical supplies and commercial quantities of any product candidate that Catalyst commercializes following approval for marketing by applicable regulatory authorities. Catalyst also expects to rely on one or more third-party contractors to manufacture its product candidates for use in its clinical trials. Reliance on such third-party contractors entails risks, including:

- the inability to identify and negotiate manufacturing and supply agreements with suitable manufacturers;
- manufacturing delays if its third-party contractors give greater priority to the supply of other products over its product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between Catalyst and them;
- the possible termination or nonrenewal of agreements by third-party contractors at a time that is costly or inconvenient for Catalyst;
- the possible breach by the third-party contractors of its agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the possible misappropriation of its proprietary information, including its trade secrets and know-how.

Catalyst may incur delays in product development resulting from the need to identify or qualify manufacturers for its product candidates. Catalyst's current and anticipated future dependence upon others for the manufacture of its product candidates may adversely affect its future profit margins and its ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Catalyst is subject to many manufacturing risks, any of which could substantially increase its costs and limit supply of its product candidates and any future products.

To date, Catalyst's product candidates have been manufactured by third-party manufacturers solely for preclinical studies and relatively small clinical trials. The process of manufacturing its complement associated therapeutic product candidates is complex, highly regulated and subject to several risks, including:

- the manufacturing facilities in which its products are made could be adversely affected by equipment failures, labor and raw material shortages, financial difficulties of its contract manufacturers, including as a result of the evolving effects of the COVID-19 pandemic, natural disasters, power failures, local political unrest and numerous other factors; and
- any adverse developments affecting manufacturing operations or the scale up of manufacturing operations for its products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of its product candidates. Catalyst may also have to record inventory

write-offs and incur other charges and expenses for product candidates or drug substances that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

Specifically, Catalyst plans to enter into various development, manufacturing and clinical supply services agreements with third-party manufacturers for drug substance and drug product manufacturing of its product candidate Hydronidone. If Catalyst's third-party manufacturers are not able to provide sufficient quantities or quality of its of product candidates on a timely basis, or at all, whether due to production shortages or other supply delays or interruptions resulting from the ongoing COVID-19 pandemic or otherwise, its preclinical trials, clinical trials or regulatory approvals, as applicable, may be delayed. Significant portions of its research and development resources are focused on manufacturing. If any of its third-party manufacturers experiences difficulties in scaling production or experiences product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error or improper storage conditions, the potential trials of the affected product candidate would be delayed, perhaps substantially, which could materially and adversely affect its business.

Catalyst has minimal process development capabilities and has access only to external manufacturing capabilities. Catalyst does not have, and Catalyst does not currently plan to acquire or develop, the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in clinical trials or commercialization. Any delay or interruption in the supply of clinical trial material or preclinical trial material could delay the completion of clinical trials or preclinical trials, increase the costs associated with maintaining such trial programs and, depending upon the period of delay, require Catalyst to commence new clinical trials or preclinical trials at additional expense or terminate the trials completely.

Catalyst and its contract manufacturers will be subject to significant regulation with respect to manufacturing its products. The manufacturing facilities on which Catalyst will rely may not continue to meet regulatory requirements and have limited capacity.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including any contract manufacturers for its product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with GMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of its product candidates that may not be detectable in final product testing. Catalyst or its contract manufacturers must supply all necessary documentation in support of an NDA on a timely basis and must adhere to the FDA's GLP and GMP regulations enforced by the FDA through its facilities inspection program. Catalyst's facilities and quality systems and the facilities and quality systems of some or all its third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of its product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of its product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection or do not have a GMP compliance status acceptable for the FDA, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit its manufacturing facilities or those of its third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of its product specifications or applicable regulations occurs independent of such an inspection or audit, Catalyst or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for Catalyst or a third-party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon Catalyst or third parties with whom Catalyst contracts could materially harm its business.

If Catalyst or any of its third-party manufacturers fails to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, its business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a NDA supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in its desired clinical and commercial timelines.

These factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of its product candidates, cause Catalyst to incur higher costs and prevent Catalyst from commercializing its products successfully. Furthermore, if its suppliers fail to meet contractual requirements, and Catalyst is unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, its clinical studies may be delayed, or Catalyst could lose potential revenue.

Catalyst relies on third parties to conduct certain aspects of its preclinical studies and any clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such tasks or trials.

Catalyst relies on third parties such as contract research organizations ("CROs"), medical institutions and clinical investigators to conduct certain aspects of preclinical development, including assay development and testing, and to enroll qualified patients and conduct, supervise and monitor clinical trials. Catalyst's reliance on these third parties for preclinical and clinical development activities reduces its control over these activities. Catalyst's reliance on these third parties, however, will not relieve Catalyst of its regulatory responsibilities, including ensuring that its clinical studies are conducted in accordance with good clinical practices, and the investigational plan and protocols contained in the relevant regulatory application, such as an investigational new drug application ("IND"). In addition, the CROs with whom Catalyst contracts may not complete activities on schedule or may not conduct its preclinical studies or clinical studies in accordance with regulatory requirements or its clinical study design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, its efforts to complete development and obtain regulatory approvals for, and to commercialize, its product candidates may be delayed or prevented.

Risks Related to Employee Matters, Managing Growth and Catalyst's Business Operations

Catalyst's future success depends on its ability to retain key executives and to attract, retain and motivate qualified personnel.

Catalyst's ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon its ability to attract and retain highly qualified managerial, scientific and medical personnel. Catalyst is highly dependent on its executive management and scientific personnel. Catalyst does not maintain "key man" insurance policies on the lives of these individuals or the lives of any of its other employees. In addition, Catalyst will need to add personnel to achieve its business objectives. The loss of the services of any of its executive officers, other key employees, and its inability to find suitable replacements, or its inability to hire new clinical development and manufacturing personnel, could result in delays in product development and harm its business.

Catalyst conducts operations at its facility in the San Francisco Bay Area. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in its market is intense and may limit its ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at Catalyst, in addition to salary and cash incentives, Catalyst has provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in Catalyst's stock price that are beyond its control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite its efforts to retain valuable employees, members of management and scientific and development teams have terminated and may terminate their employment with Catalyst on short notice. Catalyst's employees are under at-will employment arrangements, which means that any of its employees can leave employment with Catalyst at any time, with or without notice. Failure to retain, replace or recruit personnel could harm its business.

Catalyst's employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

Catalyst is exposed to the risk of fraud or other misconduct by its employees, principal investigators, consultants and collaborators. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, to provide accurate information to the FDA and non-U.S. regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to disclose unauthorized activities to Catalyst. 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 may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained during clinical studies that could result in regulatory sanctions and cause serious harm to its reputation. It is not always possible to identify and deter employee misconduct, and the precautions Catalyst takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting Catalyst 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 Catalyst and Catalyst is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of significant fines or other sanctions.

Catalyst will continue to incur significant costs as a result of operating as a public company, and its management is required to devote substantial time to compliance initiatives.

As a public company, Catalyst has and will continue to incur significant legal, accounting and other expenses, including costs associated with public company reporting and corporate governance requirements, in order to comply with the rules and regulations imposed by the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection, as well as rules implemented by the SEC and Nasdaq. Stockholder activism, the 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 Catalyst operates its business in ways that are not currently anticipated. Its management and other personnel need to devote a substantial amount of time to these compliance initiatives. In addition, these rules and regulations make it difficult and expensive for Catalyst to obtain director and officer liability insurance, and Catalyst may be required to incur substantial costs to maintain its current levels of such coverage. Catalyst expects that it will annually incur significant expenses to comply with the requirements imposed on Catalyst as a public company.

Risks Related to Catalyst's Intellectual Property

If Catalyst is unable to obtain, protect or enforce intellectual property rights related to its product candidates, Catalyst may not be able to compete effectively in its markets.

Catalyst relies upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to its product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. Third parties may challenge the validity, enforceability or scope of its patents, which may result in those patents being narrowed or invalidated. The patent applications that Catalyst owns may fail to result in issued patents with claims that cover its product candidates in the United States or in other foreign countries. Furthermore, even if they are unchallenged, its patents and patent applications may not adequately protect its intellectual property, provide exclusivity for its product candidates or prevent others from designing around its claims. Certain of its patents also cover processes, for which enforcement can be difficult. Any of these outcomes could impair its ability to prevent competition from third parties that may have an adverse impact on its business.

If the patents or patent applications Catalyst holds or has in-licensed for its programs or product candidates are invalidated or fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for its product candidates, it could threaten its ability to commercialize future products. Further, if Catalyst encounters delays in regulatory approvals, the period of time during which Catalyst could market a product candidate under patent protection could be reduced. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a

patent, and the protection it affords, is limited. Once the patent life has expired for a product, Catalyst may be subject to competition from generic medications.

In addition to the protection afforded by patents, Catalyst relies on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that Catalyst elects not to patent and other elements of its product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. Catalyst seeks to protect its proprietary technology and processes, in part, by entering into confidentiality agreements with its employees, consultants, scientific advisors and contractors. Catalyst also seeks to preserve the integrity and confidentiality of its data and trade secrets by maintaining the physical security of its premises and physical and electronic security of its information technology systems. While Catalyst has confidence in these individuals, organizations and systems, agreements or security measures may be breached, and Catalyst may not have adequate remedies for any breach. In addition, its trade secrets may otherwise become known or be independently discovered by competitors.

Although Catalyst expects all of its employees and consultants to assign their applicable inventions to Catalyst, and all of its employees, consultants, advisors and any third parties who have access to its proprietary know-how, information or technology to enter into confidentiality agreements, Catalyst cannot provide guarantee that all such agreements have been duly executed or that its trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to its trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of its trade secrets could impair its competitive position and may have a material adverse effect on its business. Additionally, if the steps taken to maintain its trade secrets are deemed inadequate, Catalyst may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover its trade secrets and proprietary information.

Further, filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and Catalyst's intellectual property rights in some countries outside the United States are less extensive than those in the United States. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, Catalyst may encounter significant problems in protecting and defending its intellectual property both in the United States and abroad. If Catalyst is unable to prevent material disclosure of the non-patented intellectual property related to its technologies to third parties, and there is no guarantee that Catalyst will have any such enforceable trade secret protection, Catalyst may not be able to establish or maintain a competitive advantage in its market, which could materially adversely affect its business, results of operations and financial condition.

Third-party claims of intellectual property infringement or challenging the inventorship or ownership of its patents may prevent or delay its development and commercialization efforts.

Catalyst's commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which Catalyst is pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that its product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that the manufacture, use or sale of its product candidates infringes patents held by such third parties, or that Catalyst is employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of its product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that its product candidates or current products may infringe.

In addition, Catalyst has received confidential and proprietary information from third parties, and Catalyst employs individuals who were previously employed at other biotechnology or pharmaceutical companies. Catalyst may be subject to claims that its employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or its employees' former employers. Litigation may be necessary to defend against these claims.

Parties making claims against Catalyst may obtain injunctive or other equitable relief that could effectively block its ability to further develop and commercialize one or more of its product candidates unless Catalyst redesigned infringing products (which may be impossible) or obtained a license under the applicable patents (which may not be available on commercially reasonable terms or at all), or until such patents expire.

Catalyst may be involved in lawsuits to protect or enforce its patents.

Competitors may infringe Catalyst's patents. To counter infringement or unauthorized use, Catalyst or its collaborators may be required to file infringement claims that can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one of Catalyst's patents 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 its patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of Catalyst's patents at risk of being invalidated or interpreted narrowly and could put its patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by Catalyst may be necessary to determine the priority of inventions with respect to its patents or patent applications or those of its licensors. An unfavorable outcome could require Catalyst to cease using the related technology or to attempt to license rights from the prevailing party. Catalyst's business could be harmed if the prevailing party does not offer Catalyst a license on commercially reasonable terms. Catalyst may not be able to prevent, alone or with its licensors, misappropriation of its 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 its 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 its common stock.

Intellectual property litigation could cause Catalyst to spend substantial resources and distract its personnel from their normal responsibilities.

Even if resolved in Catalyst's favor, litigation or other legal proceedings relating to intellectual property claims, regardless of their merit, would cause Catalyst to incur significant expenses, and could distract its technical and management personnel from their normal responsibilities. In the event of a successful claim of infringement against Catalyst, Catalyst may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, in addition to paying royalties, redesign infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of its common stock. Such litigation or proceedings could substantially increase its operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Catalyst may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of its competitors may be able to sustain the costs of such litigation or proceedings more effectively than Catalyst can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise its ability to compete in the marketplace.

Catalyst may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third-party may hold intellectual property, including patent rights, that is important or necessary to the development of its products. It may be necessary for Catalyst to use the patented or proprietary technology of third parties to

commercialize its products, in which case Catalyst would be required to obtain a license from these third parties on commercially reasonable terms, or its business could be harmed, possibly materially.

Risks Related to Regulatory Approval of Catalyst's Product Candidates and Other Compliance Matters

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If Catalyst is not able to obtain, or if there are delays in obtaining, required regulatory approvals, Catalyst will not be able to commercialize its product candidates, including Hydronidone, and its ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Hydronidone currently has one active IND application with the FDA in the United States for the treatment of liver fibrosis associated with a broad spectrum of chronic liver diseases. In the future, it is expected that an additional IND will be filed for Hydronidone specifically for NASH, and Catalyst may file additional IND applications for future indications or future product candidates. If any such future IND is not approved by the FDA, Catalyst's clinical development timeline may be negatively impacted and any future clinical programs may be delayed or terminated. As a result, Catalyst may be unable to obtain regulatory approvals or successfully commercialize its products.

Catalyst cannot guarantee that any preclinical studies and clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of its product candidates is susceptible to the risk of failure at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a suitable population of patients, the occurrence of severe or medically or commercially unacceptable adverse events, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a drug product is not approvable. It is possible that even if one or more of its product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of its clinical trials. Conversely, as a result of the same factors, its clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any.

Catalyst cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, Catalyst cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of Catalyst's product candidates, including Catalyst's lead product candidate Hydronidone, Catalyst must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that Catalyst's product candidates are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, Catalyst's product candidates, including Hydronidone, may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude Catalyst's obtaining marketing approval.

The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that Catalyst's data are insufficient for approval and require additional preclinical, clinical or other data. Catalyst's product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of Catalyst's clinical trials;
- Catalyst may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; serious and unexpected drug-related side effects may be experienced by participants in Catalyst's clinical trials or by individuals using drugs similar to Catalyst's product candidates;

- Catalyst may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; the FDA or comparable foreign regulatory authorities may disagree with Catalyst's interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of Catalyst's product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and Catalyst may be required to conduct additional clinical trials;
- the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of Catalyst's product candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which Catalyst contracts for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering Catalyst's clinical data insufficient for approval.

The approval requirements for Catalyst's product candidates are likely to vary by jurisdiction such that success in one jurisdiction is not necessarily predicative of success elsewhere.

Catalyst may experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent institutional review board ("IRB");
- recruiting suitable patients to participate in trials;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; and
- manufacturing sufficient quantities of qualified materials under Current Good Manufacturing Practice ("cGMPs") regulations and applying them on a subject-by-subject basis for use in clinical trials.

Catalyst could also experience delays in obtaining approval if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of its product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles given the serious nature of the diseases for the core indications for its product candidates. Additionally, a clinical trial may be suspended or terminated by Catalyst, the IRBs for the institutions in which the trials are being conducted, the Data Monitoring Committee for the trial, or by the FDA or other regulatory authorities for a number of reasons, including failure to conduct the clinical trial in accordance with regulatory requirements or its clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues, or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, the FDA review and approval process could be delayed by any future shutdown of the U.S. government, and its development activities could be harmed or delayed as a result. If Catalyst experiences termination of, or delays in the completion of, any clinical trial of its product candidates, its ability to commercialize its product candidates will be harmed and its ability to generate revenue will be materially impaired. Additionally, delays in completing trials will increase costs, delay Catalyst's product development and approval process, and impair its ability to commence product sales and generate revenue. Many of the factors that could create or lead to a delay in the commencement or completion of clinical trials may lead to the denial of regulatory approval for its product candidates.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in Catalyst's failing to obtain regulatory approval to market Catalyst's product candidates, including Hydronidone, which would significantly harm Catalyst's business, results of operations and prospects.

If Catalyst were to obtain approval, regulatory authorities may approve any of Catalyst's product candidates, including Hydronidone, for fewer or more limited indications than Catalyst requests, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If Catalyst is not able to obtain, or if there are delays in obtaining, required regulatory approvals for Catalyst's product candidates, including Hydronidone, Catalyst will not be able to commercialize, or will be delayed in commercializing, Catalyst's product candidates and Catalyst's ability to generate revenue will be materially impaired.

Catalyst is developing Hydronidone for the treatment of NASH, an indication for which there are no approved products. The requirements for approval of Hydronidone by the FDA and comparable foreign regulatory authorities may be difficult to predict and may change over time, which makes it difficult to predict the timing and costs of the clinical development.

Catalyst is developing Hydronidone for the treatment of NASH, an indication for which there are no approved products. Although there are guidelines issued by the FDA for the development of drugs for the treatment of NASH, the development of a novel product candidate such as Hydronidone may be more expensive and take longer than for other, better known or extensively studied product candidates. As other companies are in later stages of clinical trials for their potential NASH therapies, Catalyst expects that the path for regulatory approval for NASH therapies may continue to evolve in the near term as these other companies refine their regulatory approval strategies and interact with regulatory authorities. Such evolution may impact Catalyst's future clinical trial designs, including trial size and endpoints, in ways that Catalyst cannot predict today. In particular, regulatory authority expectations about liver biopsy data may evolve especially as more information is published about the inherent variability in liver biopsy data. Certain of Catalyst's competitors have experienced regulatory setbacks for NASH therapies following communications from the FDA. Catalyst currently does not know the impact, if any, that these setbacks could have on the path for regulatory approval for NASH therapies generally or for Hydronidone.

Catalyst's anticipated development costs would likely increase if development of Hydronidone or any future product candidate is delayed because Catalyst is required by the FDA to perform studies or trials in addition to, or different from, those that Catalyst currently anticipates, or make changes to ongoing or future clinical trial designs. In addition, if Catalyst is unable to leverage our safety database for NASH indications, Catalyst may be required to perform additional trials, which would result in increased costs and may affect the timing or outcome of its clinical trials. In addition, Hydronidone may not be developed as a monotherapy, but as a part of a combination therapy, which will add to the complexity of clinical development and may cause further delays in Hydronidone's development and affect Catalyst's costs and divert management's resources.

If Catalyst is required by the FDA to obtain approval of a companion diagnostic test in connection with approval of any of Catalyst's product candidates, including Hydronidone, and Catalyst fails to obtain or face delays in obtaining FDA approval of a diagnostic device, Catalyst will not be able to commercialize such product candidate and Catalyst's ability to generate revenue will be materially impaired.

If safe and effective use of any of Catalyst's product candidates depends on an in vitro diagnostic that is not otherwise commercially available, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves Catalyst's product candidates, if at all. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, Catalyst may be required to develop or obtain

one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostics is time-consuming and costly. If the FDA or a comparable foreign regulatory authority requires approval of a companion diagnostic for any of Catalyst's product candidates, including Hydronidone, whether before or after it obtains marketing approval, Catalyst, and/or future collaborators, may encounter difficulties in developing and obtaining approval for such product candidate. Any delay or failure by Catalyst or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate. Catalyst may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent Catalyst from completing Catalyst's clinical trials or commercializing Catalyst's product candidates, if approved, on a timely or profitable basis, if at all.

Catalyst's relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose Catalyst to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which Catalyst obtains marketing approval. Catalyst's future arrangements with third-party payors and customers may expose Catalyst to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which Catalyst would market, sell and distribute its products. As a pharmaceutical company, even though Catalyst does not and may not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to its business. These regulations include:

- the Federal Healthcare Anti-Kickback Statute that 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, or in return for, 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 a federal healthcare program such as Medicare and Medicaid, and which will constrain its marketing practices and the marketing practices of its licensees, educational programs, pricing policies, and relationships with healthcare providers or other entities;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent, and which may expose entities that provide coding and billing advice to customers to potential criminal and civil penalties, including through civil whistleblower or qui tam actions, and including as a result of claims presented in violation of the Federal Healthcare Anti-Kickback Statute, the Stark Law or other healthcare-related laws, including laws enforced by the FDA;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services that, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal physician sunshine requirements under the ACA, which requires manufacturers of approved drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services, information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

- the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws requiring pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and which may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state and foreign laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws such as HIPAA, thus complicating compliance efforts.

Efforts to ensure that its business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that its business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Catalyst's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, Catalyst may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of its operations. If any physicians or other healthcare providers or entities with whom Catalyst expects to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Catalyst's results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions.

All jurisdictions in which Catalyst conducts its research, development, manufacturing and commercialization activities regulate these activities in great depth and detail. Obtaining regulatory approvals is a lengthy, expensive and uncertain process. Catalyst intends to focus its activities in the major markets of the PRC and the United States. These geopolitical areas all have strict regulation on medical devices, and, in doing so, they employ broadly similar regulatory strategies, including regulation of product development, approval, manufacturing, sales and marketing and distribution of medical devices. However, regulatory regimes vary in different regions, which makes regulatory compliance more complex and costly for companies like Catalyst that plan to operate in each of these regions.

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. In the United States, the ACA was enacted in 2010 to expand healthcare coverage. Since then, numerous efforts have been made to repeal, amend or administratively limit the ACA in whole or in part. For example, the Tax Cuts and Jobs Act, signed into law by President Trump in 2017, repealed the individual health insurance mandate, which is considered a key component of the ACA. In December 2018, a Texas federal district court struck down the ACA on the grounds that the individual health insurance mandate is unconstitutional, although this ruling has been stayed pending appeal. The ongoing challenges to the ACA and new legislative proposals have resulted in uncertainty regarding the ACA's future viability and destabilization of the health insurance market. The resulting impact on its business is uncertain and could be material.

Efforts to control prescription drug prices could also have a material adverse effect on its business. For example, in 2018, President Trump and the Secretary of the U.S. Department of Health and Human Services released the "American Patients First Blueprint" and have begun implementing certain portions. The initiative includes proposals to increase generic drug and biosimilar competition, enable the Medicare program to negotiate drug prices more directly and improve transparency regarding drug prices and ways to lower Catalyst consumers' out-of-pocket costs. The Trump administration also proposed to establish an "international pricing index" that would be used as a benchmark to determine the costs and potentially limit the reimbursement of drugs under Medicare Part B. Among other pharmaceutical manufacturer industry-related proposals, Congress has proposed bills to alter the benefit structure to increase manufacturer contributions in the catastrophic phase. The volume of drug pricing-related bills dramatically increased under the previous Congress, and the resulting impact on its business is uncertain and could be material. The extent to which the 118th Congress will continue this approach is uncertain.

The IRA provides the Centers for Medicare & Medicaid Services ("CMS") with the ability to directly negotiate prescription drug and biologic prices with manufacturers and to cap out-of-pocket spending for Medicare Part D enrollees. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics covered under Medicare Parts B and D that lack generic or biosimilar competition. Price negotiations for Part D begin in 2023. Taking effect in 2023, the IRA provides a new "inflation rebate" that requires drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Parts B or D increases faster than the rate of inflation. The IRA contains a number of other provisions intended to reduce drug spending and the federal deficit, and the IRA's impact on competition and commercialization is uncertain but could be material.

In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in 2017, California's governor signed a prescription drug price transparency state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Both Congress and state legislatures are considering various bills that would reform drug purchasing and price negotiations, allow greater use of utilization management tools to limit Medicare Part D coverage, facilitate the import of low priced drugs from outside the United States and encourage the use of generic drugs. Such initiatives and legislation may cause added pricing pressures on its products.

Changes to the Medicaid program at the federal or state level could also have a material adverse effect on its business. Proposals that could impact coverage and reimbursement of its products, including giving states more flexibility to manage drugs covered under the Medicaid program and permitting the re-importation of prescription medications from Canada or other countries, could have a material adverse effect by limiting its products' use and coverage. Furthermore, state Medicaid programs could request additional supplemental rebates on its products as a result of an increase in the federal base Medicaid rebate. To the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, they could use the enactment of these increased rebates to exert pricing pressure on its products, and the adverse effects may be magnified by their adoption of lower payment schedules.

Other proposed regulatory actions affecting manufacturers could have a material adverse effect on its business. It is difficult to predict the impact, if any, of any such proposed legislative and regulatory actions or resulting state actions on the use and reimbursement of its products in the United States, but its results of operations may be adversely affected.

Catalyst is subject to evolving privacy and data protection laws, including HIPAA and the EU General Data Protection Regulation (EU) 2016/679 ("GDPR"). If Catalyst fails to protect personal information or comply with existing or future data protection regulations, its business, financial condition, results of operations and prospects may be materially adversely affected.

Numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability, integrity, and other processing of personal information. HIPAA establishes a set of national privacy and security standards for the protection of protected health information (as defined in HIPAA) ("PHI") by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. HIPAA requires covered entities and business associates, such as Catalyst, to develop and maintain policies with respect to the protection of, use and disclosure of electronic PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a data breach.

The collection and use of personal health data and other personal data in the EU is governed by the provisions of the GDPR, which came into force in May 2018, related data protection laws in individual EU Member States as well as implementations of the GDPR in the European Economic Area. The GDPR establishes a number of strict requirements and restrictions applicable to the processing (processing includes collecting, analyzing and transferring) of personal data (i.e., data which identifies an individual or from which an individual is identifiable) in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the notification obligations to the national data protection authorities and or data subjects (in particular in case of a data breach), and the security and confidentiality of the

personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national legislation. Furthermore, it affords various rights to individuals (e.g., the right to access or erasure of personal data).and imposes potential penalties for breaches of up to 4.0% of the annual worldwide turnover or €20 million, whichever is greater. In case of a breach of the GDPR, individuals (e.g., study subjects) may also have a right to compensation for financial or non-financial losses (e.g., distress).

There may be circumstances under which a failure to comply with the GDPR, or the exercise of individual rights under the GDPR, would limit Catalyst's ability to utilize clinical trial data collected on study subjects. Furthermore, there is a growing trend towards the required public disclosure of clinical trial data in the EU, which adds to the complexity of obligations relating to processing health data from clinical trials. Such public disclosure obligations are provided in the new EU Clinical Trials Regulation (EU CTR), EMA disclosure initiatives and voluntary commitments by industry. Failing to comply with these obligations could lead to government enforcement actions and significant penalties, harm to reputation, and adversely impact the business and operating results. The uncertainty regarding the interplay between different regulatory frameworks, such as the CTR and the GDPR, further adds to the complexity.

In addition, Catalyst is subject to various U.S. state laws which may require Catalyst to modify its data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

If Catalyst fails to comply with environmental, health and safety laws and regulations, Catalyst could become subject to fines or penalties or incur costs that could harm its business.

Catalyst is 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. From time to time and in the future, its operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if Catalyst contracts with third parties for the disposal of these materials and waste products, Catalyst cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of its hazardous materials, Catalyst could be held liable for any resulting damages, and any liability could exceed its resources. Catalyst also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Catalyst maintains workers' compensation insurance to cover Catalyst for costs and expenses Catalyst may incur due to injuries to its employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, Catalyst does not maintain insurance for environmental liability or toxic tort claims that may be asserted against Catalyst.

In addition, Catalyst may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair its research, development or production efforts that could adversely affect its business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Even if Catalyst receives regulatory approval of Catalyst's product candidates, including Hydronidone, Catalyst will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and Catalyst may be subject to penalties if Catalyst fails to comply with regulatory requirements or experience unanticipated problems with Catalyst's product candidates.

Any regulatory approvals that Catalyst may receive for Catalyst's product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, including Hydronidone, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve Catalyst's product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or comparable foreign regulatory authorities approve Catalyst's product candidates, Catalyst's product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United

States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs for any clinical trials that Catalyst conducts following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.

Catalyst identified a material weakness in its internal control over financial reporting in its consolidated financial statements for the year ended December 31, 2021. If Catalyst fails to maintain effective internal control over financial reporting, Catalyst may not be able to accurately or timely report its financial condition or results of operations, which may adversely affect its business and share price.

In connection with the preparation and audit of its consolidated financial statements for the year ended December 31, 2021, a material weakness was identified in Catalyst's internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of its consolidated financial statements will not be prevented or detected on a timely basis. Catalyst's material weakness related to the following control deficiency: Catalyst did not design and maintain effective controls related to the review of certain contracts, including the proper application of U.S. GAAP. Specifically, Catalyst did not design and maintain controls to properly review the retention bonuses granted to its employees in November 2021 after its reduction in workforce to assess the appropriate accounting treatment under U.S. GAAP.

While Catalyst took steps to remediate the material weakness, Catalyst cannot assure you that the measures Catalyst has taken to date and may take in the future will prevent or avoid potential future material weakness. The effectiveness of its internal control over financial reporting is subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the possibility of human error and the risk of fraud. If Catalyst is unable to record, process and report financial information accurately, and to prepare financial statements within the time periods specified by the forms of the SEC, Catalyst could be adversely affected which, in turn, may adversely affect its reputation and business and the market price of its common stock. In addition, any such failures could result in litigation or regulatory actions by the SEC or other regulatory authorities, loss of investor confidence, delisting of its securities and harm to its reputation and financial condition, or diversion of financial and management resources from the operation of its business.

Risks Related to Commercialization of Catalyst's Product Candidates

Even if any of its product candidates receives marketing approval, Catalyst may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of its product candidates receives marketing approval, Catalyst may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, to date, no specific therapeutic drugs treating HBV-associated liver fibrosis have been approved worldwide, and doctors may not accept or use Hydronidone as a treatment for liver fibrosis even if Hydronidone receives marketing approval. If its product candidates do not achieve an adequate level of acceptance, Catalyst may not generate significant product revenues and Catalyst may not become profitable. The degree of market acceptance of its product candidates, if approved for commercial sale, will depend on several factors, including:

- The efficacy and safety profile of Hydronidone compared with other competitor anti-fibrosis treatments;
- Catalyst's ability to offer its products for sale at competitive prices;
- the convenience of TID dosing compared with alternative treatments;
- patient understanding of NASH and associated fibrosis and its progressive nature and need for treatment;
- improvement of confirmatory-diagnosis and monitoring of NASH and associated fibrosis;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;

- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of its products together with other medications.

Catalyst's product candidates are years away from regulatory approval.

Catalyst's development candidates are not expected to be commercially available for several years, if at all. Further, the commercial success of product candidates will depend upon its acceptance by physicians, individuals, third-party payors and other key decision-makers as a therapeutic and cost-effective alternative to products available at the time, which may include competing products currently under development by others. See the risk factor titled "—Catalyst faces substantial competition that may result in others discovering, developing or commercializing products before or more successfully than Catalyst does." If Catalyst is unable to successfully develop, obtain regulatory approval in a timely manner (including due to reasons that are beyond its control, such as changes in regulations or a shutdown of the federal government, including the FDA) and commercialize its development candidates, its ability to generate revenue from product sales will be significantly delayed and its business will be materially and adversely affected, and Catalyst may not be able to earn sufficient revenues to continue as a going concern.

The regulatory authorities in the United States and the EU have not approved any products for the treatment of NASH, and while there are guidelines issued by the FDA for the development of drugs for the treatment of NASH and an FDA surrogate endpoint table for drug approval, it is unclear whether the requirements for approval will change in the future or whether the FDA will rely on regulatory precedent for future regulatory approvals. Any such changes may require Catalyst to conduct new trials that could delay its timeframe and increase the costs of our programs related to Hydronidone or any future product candidate for the treatment of NASH. In addition, Catalyst cannot be certain which efficacy endpoints or presentation thereof clinical or regulatory agencies may require in a Phase 3 clinical trial of NASH or for approval of Catalyst's product candidates.

Even if the FDA or other regulatory agency approves its product candidates, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product and may impose ongoing commitments or requirements for post-approval studies, including additional research and development and clinical trials. The FDA and other agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval. Regulatory approval from authorities in foreign countries will be needed to market its product candidates in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If Catalyst fails to obtain approvals from foreign jurisdictions, the geographic market for its product candidates would be limited.

Catalyst faces substantial competition that may result in others discovering, developing or commercializing products before or more successfully than Catalyst does.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. Catalyst faces potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions. Any product candidates that Catalyst successfully develops and commercializes will compete with existing therapies and new therapies that may become available in the future.

Although there are no currently approved therapeutic drug treatments for liver fibrosis, several companies are developing product candidates in clinical studies.

Catalyst faces competition with respect to Catalyst's current product candidates and will face competition with respect to any future product candidates from segments of the pharmaceutical, biotechnology and other related industries that pursue targeted therapies for patients with NASH. If Hydronidone or Catalyst's future product candidates do not offer sustainable advantages over competing products, Catalyst may otherwise not be able to successfully compete against current and future competitors.

Catalyst's competitors may obtain regulatory approval of their products more rapidly than Catalyst may or may obtain patent protection or other intellectual property rights that limit Catalyst's ability to develop or commercialize Catalyst's product candidates. Catalyst's competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than Catalyst's products and these competitors may also be more successful than Catalyst in manufacturing and marketing their products. In addition, Catalyst will likely need to develop Catalyst's product candidates in collaboration with companion diagnostic companies, and Catalyst will face competition from other companies in establishing these future collaborations.

Catalyst's commercial opportunity in different indications could be reduced or eliminated if competitors develop and market products or therapies that are more convenient to use, more effective, less expensive, and safer to use than its products. Furthermore, if competitors gain FDA approval earlier than Catalyst does, Catalyst may be unable to establish a strong market presence or to gain market share. The key competitive factors affecting the success of all its product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors. Catalyst's product candidates, if any are approved, may compete with these existing drug and other therapies but may not be competitive with them in price. Catalyst expects that if Catalyst's product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of Catalyst's product candidates that Catalyst successfully introduces to the market will pose challenges.

Many of the companies against which Catalyst is competing or against which Catalyst may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than Catalyst does. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of its competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with Catalyst in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and individual registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, its programs.

Even if Catalyst commercializes any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives that would harm its business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, Catalyst may obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay its commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues Catalyst is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder its ability to recoup its investment in one or more product candidates, even if its product candidates obtain marketing approval.

Catalyst's ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for certain medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that Catalyst or its collaborators commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate that receives marketing approval. Obtaining and maintaining adequate reimbursement for its products may be difficult. Catalyst may be required to conduct expensive

pharmaco-economic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, Catalyst may not be able to successfully commercialize any product candidate for which Catalyst obtains marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers its costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover its costs and may not be made permanent.

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Catalyst's inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that it develops could have a material adverse effect on its operating results, ability to raise capital needed to commercialize products and overall financial condition.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit its ability to market those products and decrease its ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of Catalyst's product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of its product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, Catalyst may not be able to successfully commercialize its product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow Catalyst to establish or maintain pricing sufficient to realize a sufficient return on its investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for its product candidates. Catalyst expects to experience pricing pressures in connection with the sale of any of its product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Risks Related to Catalyst's Common Stock

The market price of Catalyst Common Stock has historically been highly volatile.

The trading price of Catalyst Common Stock has historically been highly volatile and there have been significant periods of time in which the trading volume of its common stock has been low, which can contribute to volatility in price. Additionally, the stock market in general has experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical, biopharmaceutical and biotechnology companies in particular have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to operating performance. Factors giving rise to this volatility may include:

- disclosure of clinical trial results;
- regulatory or political developments in both the United States and abroad;

- developments concerning proprietary rights, including patents and litigation matters;
- disclosure of new collaborations or other strategic transactions;
- public concern about the safety or efficacy of product candidates or technology, their components, or related technology or new technologies generally;
- public announcements by competitors or others regarding new products or new product candidates; and
- general market conditions and comments by securities analysts and investors.

Fluctuations in operating results could adversely affect the price of Catalyst's common stock.

Catalyst's operating results are likely to fluctuate significantly from quarter to quarter and year to year. These fluctuations could cause its stock price to decline. Some of the factors that may cause operating results to fluctuate on a period-to-period basis include the scope, progress, duration results and costs of preclinical and clinical development programs, as well as non-clinical studies and assessments of product candidates and programs, restructuring costs, implementation or termination of collaboration, licensing, manufacturing or other material agreements with third parties, non-recurring revenue or expenses under any such agreement, the cost, timing and outcomes of regulatory compliance, approvals or other regulatory actions and general and industry-specific economic conditions, particularly as it affects the pharmaceutical, biopharmaceutical or biotechnology industries in the United States. Period-to-period comparisons of its historical and future financial results may not be meaningful, and investors should not rely on them as an indication of future performance. Fluctuating losses may fail to meet the expectations of securities analysts or investors. Failure to meet these expectations may cause the price of its common stock to decline.

Sales of a significant number of shares of Catalyst's common stock in the public markets, or the perception that such sales could occur, could depress the market price of its common stock.

Catalyst's current trading volumes are modest, and sales of a substantial number of shares of its common stock in the public market, or the perception that these sales could occur, could cause the market price to decline. Catalyst has effective registration statements on Form S-3 that enables Catalyst to sell up to $150.0 million of securities in one or more offerings, subject to limitations under applicable SEC rules, including up to $50.0 million of common stock issuable under its Equity Distribution Agreement with Piper Sandler & Co. Any additional sales in the public market of its common stock or other securities under these shelf registration statements could adversely affect prevailing market prices for its common stock. In addition, Catalyst has outstanding options to purchase 8,678,767 shares of common stock at a weighted average exercise price of $1.42 as of December 31, 2022. If such options are exercised and the shares are sold into the open market, such sales also might make it more difficult for Catalyst to sell equity securities in the future at a time and at a price that Catalyst deems appropriate. Conversion or exercise of these securities into shares of its common stock will cause dilution to the other holders of its common stock, and all such stock may be sold in the public market after conversion or exercise, subject to restrictions under the securities laws, which may lead to a decline in the market price of its common stock.

Anti-takeover provisions in its charter documents and provisions of Delaware law may make an acquisition more difficult and could result in the entrenchment of management.

Catalyst is incorporated in Delaware. Anti-takeover provisions of Delaware law and its charter documents may make a change in control or efforts to remove management more difficult. Also, under Delaware law, its board of directors may adopt additional anti-takeover measures. The existence of the following provisions of Delaware law and its restated certificate of incorporation and amended and restated bylaws could limit the price that investors might be willing to pay in the future for shares of its common stock.

Catalyst's restated certificate of incorporation authorizes its board of directors to issue up to 5,000,000 shares of preferred stock and to determine the terms of those shares of stock without any further action by its stockholders. If the board of directors exercises this power to issue preferred stock, it could be more difficult for a third-party to acquire a majority of its outstanding voting stock and vote the stock they acquire to remove management or directors.

Catalyst's restated certificate also provides staggered terms for the members of its board of directors, and that directors may be removed by stockholders only for cause and only by vote of the holders of 66 2/3% of voting shares then outstanding. In addition, stockholders currently are not permitted to call special meetings of stockholders, or to act by

written consent without a meeting. These provisions may prevent stockholders from replacing the entire board in a single proxy contest, making it more difficult for a third party to acquire control without the consent of its board of directors. These provisions could also delay the removal of management by the board of directors with or without cause.

As a Delaware corporation, Catalyst is also subject to certain Delaware anti-takeover provisions. Under Delaware law, a publicly-held corporation may not engage in a business combination with any holder of 15% or more of its voting stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Catalyst's board of directors could rely on Delaware law to prevent or delay an acquisition.

Catalyst is a smaller reporting company, and Catalyst cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make its common stock less attractive to investors.

Catalyst has been a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and thus have been allowed to provide simplified executive compensation disclosures in its filings. Catalyst has also had certain other decreased disclosure obligations in its SEC filings. Catalyst cannot predict whether investors find its common stock less attractive because of its reliance on any of these exemptions. If some investors find its common stock less attractive as a result, there may be a less active trading market for its common stock and its stock price may be more volatile.

General Risk Factors

Catalyst has recently received a Nasdaq notice for failing to comply with the minimum bid price listing requirement and there is no assurance Catalyst will regain compliance or maintain its Nasdaq listing.

On November 2, 2022, Catalyst received a letter from the Listing Qualifications Department of Nasdaq informing Catalyst that, because the closing bid price for Catalyst's common stock listed on Nasdaq was below $1.00 for 30 consecutive trading days, Catalyst is not in compliance with the minimum bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), Catalyst has a period of 180 calendar days from November 2, 2022, or until May 1, 2023, to regain compliance with the Minimum Bid Price Requirement. If Catalyst does not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that Catalyst's common stock will be subject to delisting.

Catalyst has received such notices three times in the past six years. There can be no assurance that Catalyst will regain compliance with the Minimum Bid Price Requirement during the 180-day compliance period, secure a second period of 180 calendar days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

Catalyst's ability to publicly or privately sell equity securities and the liquidity of its common stock could be adversely affected if it is delisted from The Nasdaq Capital Market or if it is unable to transfer its listing to another stock market. If Catalyst's common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of its common stock, increased volatility in its common stock, limited availability of market quotations for its common stock, reduced liquidity in its common stock, the loss of federal preemption of state securities laws and greater difficulty in issuing additional securities and obtaining financing. In addition, delisting of Catalyst's common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in its common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in its securities at all. Delisting could also cause a loss of confidence of Catalyst's customers, collaborators, vendors, suppliers and employees, which could harm its business and future prospects.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our corporate headquarters are in South San Francisco, California, where we lease approximately 2,976 rentable square feet of office space. The lease will expire on April 30, 2023. Catalyst expects to be able to renew this lease or obtain alternative facilities on commercially reasonable terms.

Item 3. LEGAL PROCEEDINGS

On June 15, 2022, certain Company stockholders who beneficially held in the aggregate more than five percent (5%) of our common stock filed a lawsuit in Delaware Chancery Court, captioned JDS1, LLC v. Catalyst Biosciences, Inc., et al., C.A. No. 2022-0515-KSJM (Del. Ch.), against the Company and its board of directors alleging, among other things, violations of Section 271 of the Delaware General Corporation Law and breach of fiduciary duty in connection with the Company's asset sale to Vertex, as well as certain claims related to the alleged failure to disclose information related to the Vertex transaction. In August 2022, the lawsuit was dismissed with prejudice and we reimbursed JDS1, LLC for its legal and other expenses related to the litigation in the amount of $0.4 million.

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 for Common Stock

Catalyst Biosciences, Inc. is listed on the Nasdaq Capital Market under the symbol "CBIO."

Holders of Common Stock

As of March 24, 2023, there were approximately 65 holders of record of our common stock. In addition, a substantially greater number of stockholders may be "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

Dividend Policy

We have not historically declared or paid regular cash dividends on our common stock. Although our board of directors declared special cash dividends of $45.0 million and $7.6 million, which were payable on September 20, 2022 and January 12, 2023, respectively, to stockholders of record, excluding GNI for the 2023 dividend, as of the close of business on September 6, 2022 and January 5, 2023, respectively, we do not currently intend to pay any regular cash dividends in the foreseeable future.

Unregistered Sales of Securities; Use of Proceeds from Registered Securities; Issuer Purchases of Equity Securities

N/A

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.

The following discussion and analysis should be read in conjunction with Catalyst's consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties, including those set forth under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Actual results and the timing of selected events discussed below could differ materially from those expressed in, or implied by, these forward-looking statements.

Overview

F351 Asset Acquisition

On December 26, 2022, Catalyst acquired the F351 Assets from GNI Group Ltd. and GNI Hong Kong Limited (the "Sellers") pursuant to that certain F351 Agreement, by and among Catalyst and the Sellers. The F351 Assets include 15 issued or pending patents and patent applications outside of the PRC, with the last acquired issued patent expected to expire in August 2037. Under the terms of the F351 Agreement and upon the effective time of the transactions contemplated by the F351 Agreement, Catalyst issued to the Sellers equity interests with an aggregate value of $35.0 million in the form of: 6,266,521 shares of the Company's common stock and 12,340 shares of newly designated Series X convertible preferred stock ("Catalyst Convertible Preferred Stock"), which Catalyst Convertible Preferred Stock is convertible, upon the approval of the stockholders of Catalyst (as further described herein) into shares of common stock at a ratio of one (1) share of Catalyst Convertible Preferred Stock to 10,000 shares of common stock.

Subject to stockholder approval, each share of Catalyst Convertible Preferred Stock issued under the F351 Agreement is convertible into 10,000 shares of common stock. Pursuant to the F351 Agreement, Catalyst has agreed to hold a stockholders' meeting, which is expected to be held in the third quarter of 2023, to submit the following matters to the Company's stockholders for their consideration: (i) the approval of the conversion of the Catalyst Convertible Preferred Stock into shares of common stock in accordance with Nasdaq rules, or the Conversion Proposal, and (ii) if necessary or appropriate, the approval of an amendment to Catalyst's certificate of incorporation to authorize sufficient shares of common stock for the conversion of the Catalyst Convertible Preferred Stock issued pursuant to the F351 Agreement. Following stockholder approval of the Conversion Proposal, each share of Catalyst Convertible Preferred Stock is convertible into shares of the Company's common stock at any time at the option of the holder thereof, into 10,000 shares of its common stock, subject to certain limitations, including that a holder of Catalyst Convertible Preferred Stock is prohibited from converting shares of Catalyst Convertible Preferred Stock into shares of its common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (to be initially set at 9.99% and thereafter adjustable by the holder to a number between 4.99% and 19.99%) of the total number of shares of Catalyst's common stock issued and outstanding immediately after giving effect to such conversion.

Business Combination Agreement

On December 26, 2022, Catalyst, the Contributors, the Minority Holders and CPI entered into the Business Combination Agreement. The Business Combination Agreement contains the terms and conditions of the proposed business combination pursuant to which Catalyst will acquire an indirect controlling interest in BC. The closing of the Business Combination Agreement will be subject to stockholder approval at a stockholder meeting expected to be held in the third quarter of 2023 and certain customary closing conditions. If the transaction is approved by stockholders, Catalyst would issue at closing a total of up to 1,110,776,224 shares of its common stock for an indirect controlling interest in BC.

The Business Combination Agreement contains certain termination rights, including the right for it to terminate the Business Combination Agreement to enter into a definitive agreement for a superior proposal. Upon termination of the Business Combination Agreement under specified circumstances, Catalyst may be required to pay a termination fee of $2.0 million and either party, as the case may be, may be required to reimburse the other party for reasonable out-of-pocket fees and expenses incurred by such party in connection with the Business Combination Agreement, up to a maximum amount of $2.0 million.

Contingent Value Rights Agreement

Concurrent with the signing of the Business Combination Agreement, Catalyst entered into the CVR Agreement, pursuant to which each CVR Holder, excluding GNI, received one CVR issued by the Company, subject to and in accordance with the terms and conditions of the CVR Agreement, for each share of its common stock held by such holder at the CVR Record Date. Each CVR entitles the holder thereof to receive (i) certain cash payments from the net proceeds, if any, related to (a) the disposition of its legacy assets within 90 calendar days after the remainder of the Holdback Amount (as defined in the CVR Agreement) is finally determined and received by Catalyst or (b) the resolution of certain legal claims; provided, however, such period will be automatically extended for any Claim (as defined in the CVR Agreement) for an additional one-year period to the extent any Claim is appealed during the initial term, (ii) 100% of the excess cash (net of all current or contingent liabilities, including transaction-related expenses) retained by the Company in excess of $1.0 million as of the closing date of the Business Combination Agreement, and (iii) 100% of the amount actually received (net of indemnity claims, if any) by Catalyst pursuant to the asset purchase agreement dated as of May 19, 2022, by and between Catalyst and Vertex. The contingent payments under the CVR Agreement, if they become payable, will become payable to the Rights Agent (as defined in the CVR Agreement) for subsequent distribution to the CVR Holders. In the event that no such proceeds are received, or the permitted deductions under the CVR Agreement are greater than any such proceeds, CVR Holders will not receive any payment pursuant to the CVR Agreement. There can be no assurance that CVR Holders will receive any amounts. The CVRs are not transferable, except in certain limited circumstances as provided for in the CVR Agreement, will not be certificated or evidenced by any instrument, and will not be registered with the SEC or listed for trading on any exchange.

Prior to the F351 acquisition, Catalyst was engaged in the research and development of product candidates from Catalyst's protein engineering platform. In February 2022, Catalyst announced that it engaged Perella Weinberg Partners as a financial advisor to assist Catalyst in exploring strategic alternatives to monetize its assets. In March 2022, Catalyst ceased research and development activities and in May 2022, Catalyst entered into an asset purchase agreement with Vertex, pursuant to which Vertex purchased Catalyst's complement portfolio, including CB 2782-PEG and CB 4332, as well as its complement-related intellectual property, including the ProTUNE™ and ImmunoTUNE™ platforms, for $60.0 million in cash consideration. $55.0 million was received upfront and the remaining $5.0 million was retained by Vertex as a hold-back until one year after the closing date to satisfy certain post-closing indemnification obligations. Any amounts received from Vertex with respect to this hold-back will be distributed to the CVR Holders. On February 27, 2023, Catalyst signed an asset purchase agreement with GC Biopharma Corp. ("GCBP") pursuant to which GCBP acquired Catalyst's legacy rare bleeding disorders programs including marzeptacog alpha activated ("MarzAA"), dalcinonacog alpha ("DalcA") and CB-2679d-GT for a total of $6.0 million, $1.0 million payable on signing and $5.0 million payable on February 28, 2025, subject to satisfaction of post-closing indemnification obligations. In March 2023, Catalyst distributed net proceeds of approximately $0.2 million to the CVR Holders. Once received, any additional net proceeds from the transaction will be distributed to the CVR Holders. Catalyst is also pursuing certain legal claims against a third party related to payments under a 2016 asset purchase agreement, and any net recoveries related to these claims will be distributed to the CVR Holders.

Financial Operations Overview

Catalyst has no drug products approved for commercial sale and has not generated any revenue from drug product sales.

Catalyst has never been profitable and has incurred significant operating losses in each year since inception. Catalyst had net losses of $8.2 million and $87.9 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, Catalyst had an accumulated deficit of $410.9 million. As of December 31, 2022, its cash and cash equivalents balance was $21.7 million. Substantially all its operating losses were incurred in its research and development programs and in its general and administrative operations.

License and Collaboration Revenue

License and collaboration revenue consists of revenue earned for performance obligations satisfied pursuant to the License and Collaboration Agreement with Biogen entered into in December 2019 and terminated in May 2022 (the "Biogen Agreement"). Catalyst recognized collaboration revenue for reimbursable third-party vendor, out-of-pocket

and personnel costs pertaining to the Biogen Agreement, of $0.8 million and $7.3 million during the years ended December 31, 2022 and 2021, respectively.

Catalyst has not generated any revenue from the sale of any drug products and Catalyst does not expect to generate any revenue from the sale of drug products until Catalyst obtains regulatory approval of and commercialize its product candidates.

Cost of License and Collaboration Revenue

Cost of license and collaboration revenue consists of fees for research and development services payable to third-party vendors and personnel costs, corresponding to the recognition of license and collaboration revenue from Biogen. Cost of license and collaboration revenue does not include any allocated overhead costs. Catalyst recognized third-party vendor, out-of-pocket and personnel costs, most of which were reimbursable, pertaining to the Biogen Agreement of $0.8 million and $7.4 million during the years ended December 31, 2022 and 2021, respectively, and recorded such costs as cost of collaboration revenue.

Acquired In-process Research and Development Expenses

Acquired in-process research and development ("IPR&D") expense resulted from the acquisition of the F351 Assets in December 2022. The acquisition costs allocated to acquire IPR&D with no alternative future use was recorded as an expense at the acquisition date.

Research and Development Expenses

As of March 2022, Catalyst ceased the development of certain programs and during the quarter ended June 30, 2022, Catalyst ceased all research and development activities. Research and development expenses represent costs incurred to conduct research, such as the discovery and development of its product candidates. Catalyst recognizes all research and development costs as they are incurred. Nonrefundable advance payments for goods or services used in research and development are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered or services are performed, or until it is no longer expected that the goods or services will be delivered.

Research and development expenses have traditionally consisted primarily of the following:

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- laboratory and vendor expenses, including payments to consultants and third parties, related to the execution of preclinical, non-clinical and clinical studies;
- the cost of acquiring and manufacturing preclinical and clinical materials and developing manufacturing processes;
- clinical trial expenses, including costs of third-party clinical research organizations;
- performing toxicity and other preclinical studies; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies.

The table below details its internal and external costs for research and development for the period presented, excluding the acquired IPR&D (*in thousands)*. See "*Current Product Development Plans*" included elsewhere in this Annual Form 10-K for further discussion of the current research and development programs.

	Year Ended December 31,	
	2022	2021
Hemophilia	$ 2,433	$ 25,791
Complement	4,139	24,698
Personnel and other	6,135	17,198
Stock-based compensation	330	1,202
Total research and development expenses (excluding IPR&D)	$ 13,037	$ 68,889

The largest component of total operating expenses had historically been Catalyst's investment in research and development activities, including the clinical and manufacturing development of its product candidates. Costs listed for its hemophilia and complement programs above consist of clinical trial, manufacturing and research costs. Its internal resources, employees and infrastructure, identified above as personnel and other, are generally not directly tied to individual product candidates or development programs. As such, Catalyst does not maintain information regarding these costs incurred for these research and development programs on a project-specific basis.

Since Catalyst has ceased its research and development activities, Catalyst expects its aggregate research and development expenses will continue after the Business Combination Agreement.

General and Administrative Expenses

General and administrative expenses consist of personnel costs, allocated expenses, expenses for outside professional services, including legal, human resources, audit and accounting services, and other general expenses. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation. Catalyst incurs expenses associated with operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, insurance expenses, audit expenses, investor relations activities, Sarbanes-Oxley compliance expenses and other administrative expenses and professional services.

Gain on Disposal of Assets

Gain on disposal of assets resulted from the sale of Catalyst's complement portfolio and related intellectual property to Vertex in May 2022. The gain is presented net of the direct costs incurred to transact the sale and losses incurred in connection with the sale of Catalyst's property and equipment.

Results of Operations

The following table set forth its results of operations data for the periods presented *(in thousands)*:

	Year Ended December 31,			
	2022	2021	Change ($)	Change (%)
Revenue:				
Collaboration	$ 794	$ 7,338	$ (6,544)	(89)%
Operating expenses (income):				
Cost of collaboration	798	7,380	(6,582)	(89)%
Research and development	13,037	68,889	(55,852)	(81)%
General and administrative	17,366	18,963	(1,597)	(8)%
Acquired in-process research and development	35,390	—	35,390	*
Gain on disposal of assets, net	(57,186)	—	(57,186)	*
Total operating expenses	9,405	95,232	(85,827)	(90)%
Loss from operations	(8,611)	(87,894)	79,283	(90)%
Interest and other income (expense), net	717	(39)	756	*
Loss before income taxes	(7,894)	(87,933)	80,039	(91)%
Income tax expenses	348	—	348	*
Net loss	$ (8,242)	$ (87,933)	$ 79,691	(91)%

*Not meaningful

License and Collaboration Revenue

License and collaboration revenue for the years ended December 31, 2022 and 2021 consisted of reimbursable collaboration expenses from the Biogen Agreement.

Cost of License and Collaboration

Cost of license and collaboration revenue for the years ended December 31, 2022 and 2021 primarily related to reimbursable third-party vendor and personnel costs incurred pertaining to the Biogen Agreement.

Research and Development Expenses

Research and development expenses, excluding the acquired IPR&D, were $13.0 million and $68.9 million during the years ended December 31, 2022 and 2021, respectively, a decrease of approximately $55.9 million, or 81%. The decrease was due primarily to a decrease of $23.4 million in hemophilia-related costs, a decrease of $20.5 million in complement-related costs, a decrease of $11.1 million in personnel-related costs, and a decrease of $0.9 million in stock-based compensation costs. Research and development expenses for the year ended December 31, 2022 include approximately $0.6 million of severance and other costs related to its reduction-in-force.

General and Administrative Expenses

General and administrative expenses were $17.4 million and $19.0 million during the years ended December 31, 2022 and 2021, respectively, a decrease of approximately $1.6 million, or 8%. The decrease was due primarily to a decrease of $2.1 million in professional services, a decrease of $2.1 million in personnel-related costs, partially offset by an increase of $2.2 million in facilities and other administrative costs, which primarily related to transaction costs incurred in connection with the Business Combination Agreement and costs related to the Company's operating leases, an increase of $0.2 million related to the Company's allowance for doubtful accounts, and a net increase of $0.2 million related to settlements reached with Biogen and certain contract service vendors. General and administrative expenses for the year ended December 31, 2022 include approximately $0.4 million of severance and other costs related to its reduction-in-force.

Acquired In-Process Research and Development

Acquired IPR&D was $35.4 million for the year ended December 31, 2022, which related to the acquisition of the F351 Assets in December 2022. The acquisition cost allocated to acquire IPR&D with no alternative future use was recorded as an expense at the acquisition date. No acquired IPR&D expenses were incurred in 2021.

Gain on Disposal of Assets, Net

Gain on disposal of assets, net was $57.2 million for the year ended December 31, 2022, which primarily consisted of a $57.4 million gain related to the sale of its complement portfolio to Vertex in May 2022.

Interest and Other Income (Expense), Net

The $0.8 million increase in interest and other income (expense), net for the year ended December 31, 2022 compared to the year ended December 31, 2021 was primarily due to a $0.2 million gain recognized upon the extinguishment of a liability and an increase in interest income.

Recent Accounting Pronouncements

Refer to Note 3, *Summary of Significant Accounting Policies,* to Catalyst's consolidated financial statements included within Item 8 of this Annual Report on Form 10-K for a description of recent accounting pronouncements adopted and not yet adopted for the year ended December 31, 2022.

Liquidity and Capital Resources

On September 20, 2022, Catalyst paid a special, one-time cash dividend of $1.43 per share, or approximately $45.0 million, to holders of the Company's common stock. On December 27, 2022, Catalyst declared another special cash dividend of $0.24 per share, or approximately $7.6 million, to holders of the Company's common stock, excluding GNI, which was paid on January 12, 2023.

As of December 31, 2022, Catalyst had $21.7 million of cash and cash equivalents. During the year ended December 31, 2022, Catalyst had a $8.2 million net loss and $33.1 million cash used in operating activities. Catalyst has an accumulated deficit of $410.9 million as of December 31, 2022. Catalyst expects that its existing cash and cash equivalents are sufficient to support its operating expenses through 2023, assuming the Company's stockholders approve the Conversion Proposal. Catalyst's estimate as to how long the Company expects its cash and cash equivalents to be able to fund its operations is based on assumptions that may prove to be wrong, and it could use the Company's available capital resources sooner than it currently expects. Further, changing circumstances, some of

which may be beyond Catalyst's control, could cause it to consume capital significantly faster than currently anticipated, and the Company may need to seek additional funds sooner than planned.

In connection with the F351 Agreement, Catalyst issued Catalyst Convertible Preferred Stock to GNI. Catalyst is obligated to seek stockholder approval for the conversion of the Catalyst Convertible Preferred Stock into common stock. In the event that the Company fails to timely hold the stockholders' meeting or fails to obtain stockholder approval of the Conversion Proposal, then the holders of the Catalyst Convertible Preferred Stock would be entitled to require Catalyst to redeem, in cash, the shares of common stock underlying its Catalyst Convertible Preferred Stock at a price per share equal to the fair value of the common stock. If Catalyst is forced to redeem a significant amount of shares underlying the Catalyst Convertible Preferred Stock, it could, among other things, materially affect the Company's results of operations and cash usage forecasts, require Catalyst to raise additional capital and impact its ability to raise additional capital. Also, while Catalyst cannot predict the amount with any level of certainty, there is a level of cash settlement at which, if it is exceeded, could require Catalyst to make redemption payments in excess of its current liquidity. Catalyst believes that its stockholders who are entitled to vote on the Conversion Proposal at its 2023 Annual Meeting of Stockholders, which is expected to be held in the third quarter of 2023, will vote to approve the proposal. However, as the vote of the Company's stockholders is outside of its control, there is substantial doubt about Catalyst's ability to continue as a going concern within one year from the filing of this Annual Report on Form 10-K.

Catalyst expects to finance any future cash needs through a combination of divestitures of its product candidates or other assets, equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. There can be no assurance as to the timing, terms or consummation of any divestiture or financing, and the terms of any such financing may adversely affect the Company's stockholders' rights. If Catalyst raises funds through collaborations, strategic alliances or licensing arrangements with third parties, it may have to relinquish valuable rights to its technologies, product candidates or to grant licenses on terms that may not be favorable to the Company.

The following table summarizes its cash flows for the periods presented *(in thousands):*

	Year Ended December 31,	
	2022	2021
Cash used in operating activities	$ (33,096)	$ (83,755)
Cash provided by investing activities	55,426	48,189
Cash (used in) provided by financing activities	(45,011)	49,553
Net (decrease) increase in cash and cash equivalents	$ (22,681)	$ 13,987

Cash Flows from Operating Activities

Cash used in operating activities for the year ended December 31, 2022 was $33.1 million. The most significant component of its cash used was a net loss of $8.2 million. The net loss included the net gain of $57.2 million from the sale of its complement portfolio and other assets, offset by non-cash expense primarily related to IPR&D of $35.4 million that resulted from the acquisition of the F351 Assets in December 2022 in exchange for shares of the Company's stock, stock-based compensation of $1.3 million, bad debt expense of $0.2 million, and depreciation and amortization of $0.2 million. In addition, net cash outflow of $4.9 million was attributable to the change in its net operating assets and liabilities primarily as a result of a $6.2 million decrease in accounts payable, and a $1.9 million decrease in accrued compensation and other accrued liabilities, partially offset by a $1.6 million decrease in accounts and other receivables and a $1.6 million decrease in prepaid and other current assets.

Cash used in operating activities for the year ended December 31, 2021 was $83.8 million. The most significant component of its cash used was a net loss of $87.9 million. This included non-cash expenses related to stock-based compensation of $3.4 million and depreciation and amortization of $0.3 million. In addition, cash inflow of $0.5 million was attributable to the change in its net operating assets and liabilities primarily as a result of a $3.9 million decrease in prepaid and other assets, a $1.5 million decrease in accounts receivable, and a $0.5 million increase in accounts payable, offset by a $3.7 million decrease in accrued compensation and other accrued liabilities and a $1.8 million decrease in deferred revenue related to the Biogen Agreement.

Cash Flows from Investing Activities

Cash provided by investing activities for the year ended December 31, 2022 was $55.4 million, due to $55.0 million in cash proceeds from the sale of its complement portfolio to Vertex, $2.5 million due to proceeds from maturities of investments, and $0.5 million in proceeds from the sale of property and equipment, partially offset by $2.6 million in transaction costs related to the sale of its complement portfolio to Vertex.

Cash provided by investing activities for the year ended December 31, 2021 was $48.2 million, due to $49.0 million in proceeds from maturities of investments, offset by $0.8 million used in purchases of property and equipment.

Cash Flows from Financing Activities

Cash used in financing activities for the year ended December 31, 2022 was $45.0 million, due to the special dividend issued and paid in September 2022, offset by the issuance of a minimal amount of stock grants and option exercises.

Cash provided by financing activities for the year ended December 31, 2021 was $49.6 million, due to $49.3 million in net proceeds from the issuance of common stock related to its public offering in the first quarter of 2021 and $0.3 million in proceeds from ESPP purchases of common stock and stock option exercises.

Critical Accounting Polices and Estimates

The preparation of the consolidated financial statements and related disclosures in conformity with U.S. generally accepted accounting principles ("GAAP") and the Company's discussion and analysis of its financial condition and operating results require the Company's management to make judgments, assumptions and estimates that affect the amounts reported in its consolidated financial statements and accompanying notes. Catalyst's significant accounting policies and methods used in preparation of the Company's consolidated financial statements are described in Note 3, *Summary of Significant Accounting Policies*, of the Notes to the Consolidated Financial Statements of this Annual Report on Form 10-K. Management bases its estimates on historical experience and on various other assumptions it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates, and such differences may be material.

Management believes the Company's critical accounting policies and estimates discussed below are critical to understanding its historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Stock-based Compensation

The Company measures the cost of employee, non-employee and director services received in exchange for an award of equity instruments based on the fair value-based measurement of the award on the date of grant and recognize the related expense over the period during which an employee, non-employee or director is required to provide service in exchange for the award on a straight-line basis. The estimated fair value of equity awards that contain performance conditions is expensed over the term of the award once Catalyst has determined that it is probable that performance conditions will be satisfied.

Determining the fair value of stock-based awards at the grant date requires judgment. The Company uses the Black-Scholes option-pricing model to determine the fair value of stock options. The determination of the grant date fair value of options using an option-pricing model is affected by Catalyst's assumptions regarding a number of variables including the fair value of its common stock, its expected common stock price volatility over the expected life of the options, expected term of the stock option, risk-free interest rates and expected dividends. The Company records stock-based compensation as a compensation expense, net of the forfeited awards. Catalyst elected to account for forfeitures when they occur. As such, the Company recognizes stock-based compensation expense over their requisite service period based on the vesting provisions of the individual grants. See Note 10, *Stock Based Compensation*, to the consolidated financial statements included in this Annual Report on Form 10-K for more information.

F351 Asset Acquisition

On December 26, 2022, the Company completed its acquisition of the F351 Assets in accordance with the terms of the F351 Agreement. Catalyst concluded that the acquisition did not result in the acquisition of a business, as substantially all of the fair value of the assets acquired was concentrated in a single identifiable asset, the intellectual property rights (outside of the PRC) to a clinical stage drug candidate for the treatment of liver fibrosis, or the F351 Assets. Significant judgment was required in evaluating the terms of the F351 Agreement and in valuing and recording the acquired assets at fair value as well as determining whether the acquired IPR&D had an alternative future use.

Redeemable Convertible Preferred Stock

In connection with the F351 Asset acquisition, Catalyst issued shares of a newly designated series of preferred stock, the Catalyst Convertible Preferred Stock, to GNI. Each share of Catalyst Convertible Preferred Stock is convertible into 10,000 shares of common stock, subject to stockholder approval under Nasdaq rules and subject to a beneficial ownership conversion blocker. The Company classified the Catalyst Convertible Preferred Stock as temporary equity on the consolidated balance sheet because if conversion to common stock is not approved by the stockholders, the Catalyst Convertible Preferred Stock would be redeemable at the option of the holders for cash equal to the closing price of the common stock on last trading day prior to the holder's redemption request. Catalyst recorded the Catalyst Convertible Preferred Stock at its relative fair value on the date of issuance (i.e., the closing date of the F351 Asset acquisition) and did not adjust the carrying value to its redemption value since the Catalyst Convertible Preferred Stock is not currently redeemable, and it is not probable that it will become redeemable in the future at the balance sheet date. Significant judgment was required in evaluating the various rights of the Catalyst Convertible Preferred Stock and in classifying and measuring the Catalyst Convertible Preferred Stock as well as determining whether the Catalyst Convertible Preferred Stock is a participating security upon issuance.

Contingent Value Rights Liability

On December 26, 2022, the Company executed the CVR Agreement, pursuant to which each CVR Holder received one contractual CVR for each share of Catalyst common stock held by such holder. Each CVR entitles the holder thereof to receive cash payments in the future. Certain contingent payments under the CVR Agreement qualified as derivatives under ASC 815, *Derivatives and Hedging*, and were recorded as a liability on the balance sheet as of December 31, 2022. The CVR liability is considered a Level 3 instrument that is initially measured at its estimated fair value on the transaction date and subsequently remeasured at each reporting date with changes recorded in the consolidated statement of operations. The determination of the initial and subsequent fair value of the CVR liability requires significant judgment by management. Changes in any of the inputs not related to facts and circumstances existing as of the transaction date may result in a significant fair value adjustment, which can impact the results of operations in the period in which the adjustment is made.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CATALYST BIOSCIENCES, INC.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Catalyst Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Catalyst Biosciences, Inc. (the "Company") as of December 31, 2022 and 2021 and the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022 and 2021, and the consolidated results of their operations and their cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the terms of the Convertible Preferred Stock include a cash settlement feature which, provide that, if the Company's stockholders fail to approve the conversion of the Convertible Preferred Stock by September 30, 2023, the Company could be required to make cash payments to the holders of the Convertible Preferred Stock significantly in excess of its current liquidity, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 the 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the financial statements and (ii) involved especially challenging, subjective, or complex judgments. The communication of critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Asset Acquisition

As described in Note 1 to the financial statements, during the year ended December 31, 2022, the Company executed and closed an asset purchase agreement, with GNI Group Ltd. and GNI Hong Kong Limited (together "GNI") to purchase all of the assets and intellectual property rights primarily related to GNI's proprietary Hydronidone compound, other than such assets and intellectual property rights located in the People's Republic of China. The Company paid GNI $35.0 million in the form of 6,266,521 shares of the Company's common stock and 12,340 shares of newly designated Series X redeemable convertible preferred stock ("Convertible Preferred Stock"). The Convertible Preferred Stock is classified as temporary equity on the consolidated balance sheet because it would be redeemable at the option of the holders for cash if conversion to common stock is not approved by the shareholders. Concurrently with the asset purchase agreement, the Company executed a contingent value rights agreement, in which certain common stockholders received a contractual contingent value right ("CVR") for each share of common stock held by the stockholder entitling the holder to certain cash payments in the future. Certain contingent payments under the CVR agreement qualified as derivatives and were recorded as a liability on the balance sheet at fair value as of December 31, 2022. Significant management judgment was required in evaluating the various rights of the Convertible Preferred Stock and in classifying the Convertible Preferred Stock. The determination of derivative qualification and the initial and subsequent fair value of the CVR liability also required significant management judgment.

We identified the classification of the Convertible Preferred Stock and the derivative evaluation for contingent payments and the initial and subsequent valuation of the CVR under the CVR agreement as a critical audit matter due to (i) the significant management judgment required in the applicable accounting guidance; (ii) the complexity of the accounting guidance in these areas; and (iii) the significant unusual nature of the transactions. Auditing these elements involved specialized knowledge and experience in dealing with complex debt and equity arrangements.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. We obtained an understanding and evaluated the design of controls relating to the Company's accounting for significant accounting transactions. We read and analyzed the agreements and contract terms related to the Convertible Preferred Stock and CVR agreement. We evaluated the assumptions and conclusions made by the Company related to the accounting treatment of the Convertible Preferred Stock classification and CVR derivative liability, including the Company's consideration of relevant accounting standards and their analysis of the appropriate accounting treatment. We utilized personnel with specialized skill and knowledge in the relevant technical accounting guidance to assist in evaluating the appropriateness of the Company's application of the relevant accounting guidance. We tested the valuation of the Convertible Preferred Stock and utilized internal valuation specialists to assist in evaluating the appropriateness of the Company's methodology and the assumptions utilized.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2014.

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 30, 2023

Catalyst Biosciences, Inc.
Consolidated Balance Sheets
(In thousands, except shares and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 21,666	$ 44,347
Short-term investments	—	2,504
Accounts and other receivables	5,000	1,818
Prepaid and other current assets	1,540	2,807
Total current assets	28,206	51,476
Other assets, noncurrent	168	472
Right-of-use assets	66	2,744
Property and equipment, net	4	970
Total assets	$ 28,444	$ 55,662
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 194	$ 6,419
Accrued compensation	2,582	1,467
Deferred revenue	—	230
Other accrued liabilities	1,452	4,072
Dividends payable	7,558	—
CVR derivative liability	5,000	—
Operating lease liability	38	1,977
Total current liabilities	16,824	14,165
Operating lease liability, noncurrent	—	408
Total liabilities	16,824	14,573
Commitments and Contingencies (Note 8)		
Redeemable convertible preferred stock, $0.001 par value, 123,418 shares authorized; 12,340 shares issued and outstanding as of December 31, 2022 and no shares issued and outstanding as of December 31, 2021	33,309	—
Stockholders' equity (deficit):		
Common stock, $0.001 par value, 100,000,000 shares authorized; 37,756,574 and 31,409,707 shares issued and outstanding at December 31, 2022 and 2021, respectively	37	31
Additional paid-in capital	389,210	443,752
Accumulated deficit	(410,936)	(402,694)
Total stockholders' equity (deficit)	(21,689)	41,089
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 28,444	$ 55,662

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

Catalyst Biosciences, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	2021
Revenue:		
Collaboration	$ 794	$ 7,338
Operating expenses (income):		
Cost of collaboration	798	7,380
Research and development	13,037	68,889
General and administrative	17,366	18,963
Acquired in-process research and development	35,390	—
Gain on disposal of assets, net	(57,186)	—
Total operating expenses	9,405	95,232
Loss from operations	(8,611)	(87,894)
Interest and other income (expense), net	717	(39)
Loss before income taxes	(7,894)	(87,933)
Income tax expenses	348	—
Net loss	$ (8,242)	$ (87,933)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.26)	$ (2.87)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	31,545,723	30,640,977
Cash dividends paid per common share	$ 1.43	$ —
Cash dividends declared, unpaid, per common share	$ 0.24	$ —

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

Catalyst Biosciences, Inc.
Consolidated Statements of Comprehensive Loss
(In thousands)

	Year Ended December 31,	
	2022	2021
Net loss	$ (8,242)	$ (87,933)
Other comprehensive loss:		
Unrealized loss on available-for-sale debt securities	—	(5)
Total comprehensive loss	$ (8,242)	$ (87,938)

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

Catalyst Biosciences, Inc.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	(Deficit)
Balance at December 31, 2020	—	$ —	22,097,820	$ 22	$ 390,803	$ 5	$ (314,761)	$ 76,069
Stock-based compensation expense	—	—	56,912	—	3,405	—	—	3,405
Issuance of common stock from stock grants and option exercises	—	—	69,975	—	303	—	—	303
Issuance of common stock for public offering, net of issuance costs of $3,563	—	—	9,185,000	9	49,241	—	—	49,250
Unrealized loss on available-for-sale debt securities	—	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(87,933)	(87,933)
Balance at December 31, 2021	—	—	31,409,707	31	443,752	—	(402,694)	41,089
Stock-based compensation expense	—	—	32,684	—	1,342	—	—	1,342
Issuance of common stock from stock grants and option exercises	—	—	47,662	—	20	—	—	20
Issuance of common and preferred stock upon acquisition of F351 Assets	12,340	33,309	6,266,521	6	1,685	—	—	1,691
Cash dividends paid ($1.43 per share)	—	—	—	—	(45,031)	—	—	(45,031)
Cash dividends declared, unpaid ($0.24 per share)	—	—	—	—	(7,558)	—	—	(7,558)
CVR derivative liability	—	—	—	—	(5,000)	—	—	(5,000)
Net loss	—	—	—	—	—	—	(8,242)	(8,242)
Balance at December 31, 2022	12,340	$ 33,309	37,756,574	$ 37	$ 389,210	$ —	$ (410,936)	$ (21,689)

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

Catalyst Biosciences, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2022	**2021**
Operating Activities		
Net loss	$ (8,242)	$ (87,933)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	35,390	—
Stock-based compensation expense	1,342	3,405
Depreciation and amortization	230	290
Bad debt expense	200	—
Loss on lease termination	115	—
Net gain on disposal of assets	(57,186)	—
Changes in operating assets and liabilities:		
Accounts and other receivables	1,618	1,495
Prepaid and other current assets	1,609	3,880
Accounts payable	(6,225)	500
Accrued compensation and other accrued liabilities	(1,895)	(3,680)
Operating lease liability and right-of-use asset	178	41
Deferred revenue	(230)	(1,753)
Net cash flows used in operating activities	(33,096)	(83,755)
Investing Activities		
Proceeds from maturities of short-term investments	2,504	49,028
Purchases of property and equipment	—	(839)
Proceeds from the sale of property and equipment	498	—
Proceeds from the sale of complement portfolio to Vertex	55,000	—
Payment of transaction costs in connection with sale of complement portfolio to Vertex	(2,576)	—
Net cash flows provided by investing activities	55,426	48,189
Financing Activities		
Issuance of common stock for public offering, net of issuance costs	—	49,250
Payment of dividends	(45,031)	—
Issuance of common stock from stock grants and option exercises	20	303
Net cash flows (used in) provided by financing activities	(45,011)	49,553
Net (decrease) increase in cash and cash equivalents	(22,681)	13,987
Cash and cash equivalents at beginning of the period	44,347	30,360
Cash and cash equivalents at end of the period	$ 21,666	$ 44,347
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Dividend declared, unpaid	$ 7,558	$ —
CVR derivative liability	$ 5,000	$ —
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 1,850
Remeasurement of right-of-use asset due to operating lease modification	$ —	$ 624

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

1. Nature of Operations

Catalyst Biosciences, Inc. and its subsidiary (the "Company" or "Catalyst") was a biopharmaceutical company with expertise in protease engineering. Prior to ceasing research and development activities in March 2022, the Company had several protease assets that were designed to address unmet medical needs in disorders of the complement or coagulation systems. As discussed further below, the Company recently completed a purchase agreement to acquire a clinical-stage drug candidate for the treatment of NASH (nonalcoholic steatohepatitis, a severe form of nonalcoholic fatty liver disease). Concurrent with this purchase agreement, the Company entered into a separate business combination agreement to acquire an indirect controlling interest in a China-based pharmaceutical company. The Company will continue to evaluate the impact of the novel coronavirus disease ("COVID-19") pandemic on its business, operations, and cash requirements. The Company is located in South San Francisco, California and operates in one segment.

On May 19, 2022, Catalyst entered into and closed on an asset purchase agreement with Vertex Pharmaceuticals Inc. ("Vertex"), pursuant to which Vertex acquired Catalyst's complement portfolio, including CB 2782-PEG and CB 4332, as well as its complement-related intellectual property including the ProTUNE™ and ImmunoTUNE™ platforms. See Note 16, *Restructuring*. After the transaction of its complement portfolio, Catalyst's product candidates consisted of the coagulation related assets marzeptacog alfa (activated) ("MarzAA"), dalcinonacog alfa ("DalcA"), and CB 2679d-GT. MarzAA is a SQ administered next generation engineered coagulation Factor VIIa ("FVIIa") for the treatment of episodic bleeding and prophylaxis in subjects with rare bleeding disorders. DalcA is a next-generation SQ administered FIX. CB 2679d-GT is an AAV-based gene therapy construct harboring the DalcA sequence. Both MarzAA and DalcA have shown sustained efficacy and safety in mid-stage clinical trials. CB 2679d-GT has obtained preclinical proof-of-concept. Catalyst sold MarzAA, DalcA and CB-2679d-GT in February 2023 to GC Biopharma Corp. ("GCBP"). See Note 17, *Subsequent Events.*

F351 Asset Acquisition

On December 26, 2022, the Company executed and closed an Asset Purchase Agreement (the "F351 Agreement"), with GNI Group Ltd. and GNI Hong Kong Limited (together "GNI") to purchase all of the assets and intellectual property rights primarily related to the proprietary Hydronidone compound (collectively, the "F351 Assets"), other than such assets and intellectual property rights located in the People's Republic of China. At the closing of the agreement on December 26, 2022, the Company paid $35.0 million in the form of 6,266,521 shares of Catalyst common stock and 12,340 shares of newly designated Series X redeemable convertible preferred stock ("Catalyst Convertible Preferred Stock"). Each share of Catalyst Convertible Preferred Stock is convertible into 10,000 shares of common stock, subject to stockholder approval under Nasdaq rules and subject to a beneficial ownership conversion blocker. For additional information, see Note 4, *F351 Asset Acquisition* and Note 14, *Stockholders' Equity*.

Business Combination Agreement

Concurrent with the F351 Asset acquisition, the Company signed a definitive agreement with GNI Group Ltd., GNI Hong Kong Limited, GNI USA, Inc., Continent Pharmaceuticals Inc. and Shanghai Genomics, Inc. (collectively, "GNI") and other minority stockholders to acquire an indirect controlling interest in Beijing Continent Pharmaceutical Co Ltd. ("BC"), a commercial-stage pharmaceutical company based in China and majority-owned subsidiary of GNI, in exchange for newly issued shares of common stock (the "Business Combination Agreement"). The closing of the Business Combination Agreement will be subject to stockholder approval at a stockholder meeting expected to be held in the third quarter of 2023 and certain customary closing conditions. For additional information, see Note 8, *Commitments and Contingencies*.

Contingent Value Rights Agreement

Pursuant to the Business Combination Agreement, on December 26, 2022, Catalyst and the Rights Agent (as defined therein) executed a contingent value rights agreement (the "CVR Agreement"), pursuant to which each holder of Catalyst common stock as of January 5, 2023 (the "CVR Holders"), excluding GNI, received one

contractual contingent value right (a "CVR") issued by the Company for each share of Catalyst common stock held by such holder. Each CVR entitles the holder thereof to receive certain cash payments in the future. For additional information, see Note 8, *Commitments and Contingencies*.

2. Liquidity

In October 2021, the Company entered into a sales agreement with Piper Sandler & Co. ("Piper Sandler"), pursuant to which the Company could issue and sell shares of common stock, par value of $0.001 per share, through an at-the-market offering program (the "ATM Program"). The Company pays Piper Sandler 3% of the gross proceeds from any common stock sold through the sales agreement. There was no activity from the ATM Program during the years ended December 31, 2022 and 2021.

On September 20, 2022, the Company paid a special, one-time cash dividend of $1.43 per share to the Company's common stockholders of record as of close of business on September 6, 2022. The aggregate amount of the special dividend payment was approximately $45.0 million.

On December 27, 2022, the Company declared a special, one-time cash dividend of $0.24 per share, or approximately $7.6 million, to the Company's common stockholders of record as of close of business on January 5, 2022, excluding GNI. This dividend was paid on January 12, 2023.

For the year ended December 31, 2022, the Company had a net loss of $8.2 million. As of December 31, 2022, the Company had an accumulated deficit of $410.9 million and cash and cash equivalents of $21.7 million. Its primary uses of cash are to fund operating expenses and general and administrative expenditures. As part of the F351 Agreement, the Company issued 12,340 shares of Catalyst Convertible Preferred Stock, which upon stockholder approval, will be converted to 123,400,000 shares of common stock, subject to applicable beneficial ownership limitations. The terms of the Catalyst Convertible Preferred Stock include a cash settlement feature which, as described in Note 14, *Stockholders' Equity*, provide that, if the Company's stockholders fail to approve the conversion of the Catalyst Convertible Preferred Stock by June 26, 2023 (which has been extended to September 30, 2023, see Note 17, *Subsequent Events*), the Company could be required to make cash payments to the holders of Catalyst Convertible Preferred Stock significantly in excess of its current liquidity. The Company believes that stockholders who are entitled to vote on the conversion proposal at the Company's 2023 Annual Meeting of Stockholders, which is expected to be held in the third quarter of 2023, will vote to approve the proposal. However, as the vote of the Company's common stockholders is outside of the control of the Company, there is substantial doubt about its ability to continue as a going concern for at least 12 months following the issuance of these consolidated financial statements. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its subsidiary. Intercompany accounts and transactions, if applicable, have been eliminated in consolidation. The Company's consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP").

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, allowance of doubtful accounts, contingent value rights, operating lease right-of-use assets and liabilities, accrued expenses, income taxes and stock-based compensation. The Company bases its estimates on various assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Accounting Pronouncements Recently Adopted

In May 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*: Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. The amendments in ASU 2021-04 provide guidance to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments in this ASU 2021-04 are effective for all entities for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. The Company adopted ASU 2021-04 and related updates on January 1, 2022, and the adoption did not have a material impact on its consolidated financial statements.

In August 2020, FASB issued ASU 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)* to simplify accounting for certain financial instruments. ASU 2020-06 eliminates the previous models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. The amendments in this ASU are effective for public business entities for fiscal years beginning after December 15, 2021. The Company adopted ASU 2020-06 on January 1, 2022, and the adoption did not have a material impact on its consolidated financial statements.

New Accounting Pronouncements – Issued But Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*. The main objective of ASU 2016-13 is to provide financial statement users with more decision-useful information about an entity's expected credit losses on financial instruments and other commitments to extend credit at each reporting date. To achieve this objective, the amendments in this update replace the incurred loss impairment methodology currently used today with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to develop credit loss estimates. ASU 2016-13 will be effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, using a modified retrospective approach. The Company adopted ASU 2016-13 and related updates on January 1, 2023 and the adoption did not have a material impact on its consolidated financial statements.

Cash and Cash Equivalents

The Company invests its excess cash in bank deposits, consisting primarily of money market mutual funds. The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents.

Fair Value of Financial Instruments

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The fair value hierarchy requires that an entity maximize the use of observable inputs when estimating fair value. The fair value hierarchy includes the following three-level classification which is based on the market observability of the inputs used for estimating the fair value of the assets or liabilities being measured:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Inputs that are generally unobservable and typically reflect management's estimate of assumptions that market participants would use in pricing the asset or liability.

Derivative Financial Instruments

The Company evaluates its contracts to determine if those contracts qualify as derivatives under ASC 815, *Derivatives and Hedging*. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date. Any changes in fair value are recorded as non-operating, non-cash other income or expense for each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is probable within the next 12 months from the balance sheet date.

The Company determined that certain contingent payments under the CVR Agreement qualified as derivatives under ASC 815, and as such, were recorded as a liability on the balance sheet as of December 31, 2022. Refer to Note 5, *Fair Value Measurement* and Note 8, *Commitments and Contingencies*, for additional information regarding the CVR derivative liability.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which are three years for computer equipment and software, and three to seven years for furniture and leasehold improvements.

Investments

The Company invests its excess cash in investment grade, short to intermediate-term, fixed income securities and recognizes purchased securities on the settlement date. All investments have been classified as "available-for-sale" and are carried at estimated fair value based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments at the time of purchase and reevaluates such designation as of each consolidated balance sheet date. Unrealized gains and losses on available-for-sale debt securities are excluded from earnings and are reported as a component of comprehensive loss. Realized gains and losses and declines in fair value determined to be other-than-temporary, if any, on available-for-sale debt securities are included in interest and other income (expense), net. The cost of securities sold is based on the specific-identification method. Interest on short-term investments is included in interest and other income (expense), net.

Revenue Recognition

License and Collaboration Arrangements

The Company may enter into collaboration arrangements that fall under the scope Collaborative Arrangements (Topic 808). The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808 to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. The accounting for some of the activities under collaboration arrangements may be analogized to ASC 606 for distinct units of account that are reflective of a vendor-customer relationship.

Under ASC 606, in determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following 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 in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the

performance obligations based on estimated selling prices; and (v) recognition of revenue when the Company satisfies each performance obligation.

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues attributed to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement 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.

At the inception of each arrangement that contain development milestones, the Company evaluates whether the development milestones included are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not generally considered probable of being achieved until those approvals are received.

At the end of each reporting period, the Company re-evaluates the probability of achievement of any development milestones, and if necessary, adjusts its estimate of the transaction price. Any such adjustments would be recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

For research and development services, the Company elected the practical expedient to recognize revenue as the research and development services are invoiced. As the Company has a right to consideration from the collaboration agreement with Biogen International GmbH ("Biogen"), in an amount that corresponds directly with the value of the Company's performance completed to date for the research services, the Company recognized revenue related to the research services as invoiced, in line with the practical expedient in ASC 606-10-55-18.

The transaction price is allocated to each performance obligation on a relative stand-alone selling price ("SSP") basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the timing of recognition and the SSP for each performance obligation identified in the contract.

The SSP for licenses are calculated using the residual approach if the Company has not yet established a price for such license and the license has not previously been sold on a standalone basis. Otherwise, selling prices for licenses are determined using an income approach model and include key assumptions such as: development timeline, revenue forecast, commercialization expenses, discount rate and probabilities of technical and regulatory success. To estimate the SSP for research and development services, the Company uses a cost-plus margin approach.

Cost of License and Collaboration

Cost of license revenue includes sublicense fees paid or payable to Mosaic Biosciences, Inc. ("Mosaic"), incurred in the period, under the terms of the Mosaic collaboration agreement, and fees for patent development and protection paid or payable to other third-party vendors corresponding to the recognition of license revenue from the Company's collaboration agreement with Biogen. See Note 12, *Collaborations*. Cost of license revenue does not include any allocated overhead costs.

Cost of collaboration revenue includes fees for research and development services paid or payable to Mosaic and other third-party vendors and personnel cost, incurred in the period pertaining to the Company's agreement with Biogen. See Note 12, *Collaborations*. Cost of collaboration revenue does not include any allocated overhead costs.

Research and Development Expenses

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services used in research and development are initially deferred and capitalized in prepaid and other current assets. The capitalized amounts are then expensed as the related goods are delivered or services are performed, or until it is no longer expected that the goods or services will be delivered. Research and development costs consist of payroll and other personnel-related expenses, laboratory supplies and reagents, contract research and development services, materials, and consulting costs, as well as allocations of facilities and other overhead costs. Under the Company's collaboration agreement with Biogen, certain specific expenditures are reimbursed by third parties. During the years ended December 31, 2022 and 2021, $0.7 million and $6.5 million, respectively, of research and development expense was recorded as cost of collaboration revenue related to the collaboration agreement with Biogen signed in December 2019 and terminated as of May 2022.

Accrued Research and Development Expenses

Accrued expenses include estimated costs of research and development activities conducted by external service providers, which include the conduct of preclinical studies and clinical trials and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in other accrued liabilities in the consolidated balance sheet and within research and development expense in the consolidated statement of operations. These costs are a significant component of the research and development expenses. The Company records accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these external service providers.

Acquired In-Process Research and Development

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquired in-process research and development ("IPR&D") with no alternative future use is charged to expense at the acquisition date. Refer to Note 4, *F351 Asset Acquisition*, for a more detailed description of the accounting policy utilized for the recent asset acquisition.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, investments and accounts receivable. The Company's investment policy restricts cash investments to high credit quality, investment grade investments. The Company believes that it has established guidelines for investment of its excess cash that maintain safety and liquidity through its policies on high quality of investment and investment duration. The Company is exposed to credit risk of $21.4 million in the event of default by the institutions holding the cash and cash equivalents to the extent beyond the amount insured by the federal depository insurance corporation.

Accounts Receivable and Allowance for Doubtful Accounts

Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. Customer payments are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligations under the arrangements. The Company continuously monitors collections and payments from its customers and maintains a provision for estimated credit losses. The Company determines its allowance for doubtful accounts by considering a number of factors, including the length of time balances are past due, the Company's previous loss history, the customer's current ability to pay its obligations to the Company and the condition of the general economy and the industry as a whole. The Company writes off accounts receivable when they are determined to be uncollectible. For the year ended December 31, 2022, the Company recognized $0.2 million of bad debt expense and no bad debt expense was recognized during the year ended December 31, 2021.

Income Taxes

Income taxes are computed using the liability method. Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

The Company follows the authoritative guidance on accounting for uncertainty in income taxes. This guidance prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken in the Company's income tax returns. This interpretation also provides guidance on accounting for interest and penalties and associated with tax positions, accounting for income taxes in interim periods and income tax disclosures.

The Company's policy is to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary.

Stock-Based Compensation

The Company measures the cost of employee, non-employee and director services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant and recognizes the related expense over the period during which the employee, non-employee or director is required to provide service in exchange for the award on a straight-line basis. The estimated fair value of equity awards that contain performance conditions is expensed over the term of the award once the Company has determined that it is probable that performance conditions will be satisfied.

The Company uses the Black-Scholes option-pricing valuation model to estimate the grant-date fair value of stock-based awards. The determination of fair value for stock-based awards on the date of grant using an option-pricing model requires management to make certain assumptions regarding a number of variables. The Company elected to account for forfeitures when they occur. As such, the Company recognizes stock-based compensation expense, over their requisite service period, based on the vesting provisions of the individual grants.

Restructuring Charges

Costs and liabilities associated with restructuring are recorded in the period management commits to a restructuring or cost reduction plan, or executes specific actions contemplated by the plan and all criteria for liability recognition have been met. One-time employee termination costs are recognized at the time of communication to employees, unless future service is required, in which case the costs are recognized ratably over the future service period. Restructuring charges are recognized as an operating expense within the consolidated statements of operations and related liabilities are recorded within accrued compensation on the consolidated balance sheets. The Company periodically evaluates and, if necessary, adjusts its estimates based on currently available information.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

The Company has elected to combine lease and non-lease components as a single component. The lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the consolidated balance sheet as right-of-use assets, operating lease liabilities, current and operating lease liabilities, non-current.

Redeemable Convertible Preferred Stock

The Company records shares of non-voting redeemable Catalyst Convertible Preferred Stock at its relative fair value on the date of issuance. The Company applied the guidance in ASC 480-10-S99-3A, *SEC Staff Announcement: Classification and Measurement of Redeemable Securities*, and at issuance classified the Catalyst Convertible Preferred Stock as temporary equity on the consolidated balance sheet because if conversion to common stock is not approved by the shareholders, the Catalyst Convertible Preferred Stock would be redeemable at the option of the holders for cash equal to the closing price of the common stock on last trading day prior to the holder's redemption request. Refer to Note 14, *Stockholders' Equity* for additional information.

Net Loss per Share Attributable to Common Stockholders

The Company calculates basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for participating securities. The Company's redeemable convertible preferred stock contractually entitled the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in the Company's losses. As such, net losses for the periods presented were not allocated to these securities.

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for each period presented since the effects of potentially dilutive securities are antidilutive given the Company's net loss.

4. F351 Asset Acquisition

On December 26, 2022, the Company acquired the F351 Assets from GNI in accordance with the terms of the F351 Agreement as discussed in Note 1, *Nature of Operations*. Under the terms of F351 Agreement, the Company issued 6,266,521 shares of common stock and 12,340 shares of Catalyst Convertible Preferred Stock. Each share of Catalyst Convertible Preferred Stock is convertible into 10,000 shares of common stock, subject to certain conditions.

The Company concluded that the F351 acquisition was not the acquisition of a business, as substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset, the intellectual property rights (outside of China) to a clinical stage drug candidate for the treatment of liver fibrosis, or the F351 Assets.

The Company determined that the cost to acquire the F351 Assets was $35.4 million, based on the estimated fair value of the F351 Assets acquired and including direct costs of the acquisition of $0.4 million. The cost of the acquisition was allocated entirely to acquired IPR&D as no other assets or liabilities were acquired or assumed.

As the F351 Assets had not, at the time of the F351 Asset acquisition, received regulatory approval in any territory, the cost attributable to the IPR&D was expensed in the Company's consolidated statements of operations for the year ended December 31, 2022 since the acquired IPR&D had no alternative future use, as determined by the Company in accordance with GAAP.

5. Fair Value Measurements

For a description of the fair value hierarchy and fair value methodology, see Note 3, *Summary of Significant Accounting Policies*. As of December 31, 2022 and 2021, the Company's highly liquid money market funds included within cash equivalents and U.S. government agency securities are valued using Level 1 inputs. There were no transfers in or out of Level 1 and Level 2 during the periods presented. U.S. government agency securities are bonds issued by the U.S. government and are fully backed by the U.S. government. Given the frequency at which U.S. government agency securities trade and the accessibility of observable, quoted prices for such assets in active markets, they are recognized as Level 1 assets.

The following tables present the fair value hierarchy for financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2022 and 2021 *(in thousands)*:

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds[1]	$ 21,666	$ —	$ —	$ 21,666
Total financial assets	$ 21,666	$ —	$ —	$ 21,666
Financial liabilities:				
CVR derivative liability	$ —	$ —	$ 5,000	$ 5,000
Total financial liabilities	$ —	$ —	$ 5,000	$ 5,000

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds[1]	$ 44,347	$ —	$ —	$ 44,347
U.S. government agency securities[2]	2,504	—	—	2,504
Total financial assets	$ 46,851	$ —	$ —	$ 46,851

(1) Included in cash and cash equivalents on accompanying consolidated balance sheet.

(2) Included in short-term investments on accompanying consolidated balance sheet and are classified as available-for-sale debt securities.

The carrying amounts of accounts and other receivables, accounts payable, and accrued liabilities approximate their fair values due to the short-term maturity of these instruments.

Derivative Liabilities

The CVR derivative liability relates to the CVR Agreement executed in connection with the Business Combination Agreement. The fair value of this derivative liability is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. The estimated fair value of the CVR liability was determined based on the anticipated amount and timing of projected cash flows to be received from Vertex pursuant to the Vertex asset purchase agreement. As of December 31, 2022, the Company expects to receive a $5.0 million hold-back payment from Vertex in the second quarter of 2023, which will be immediately distributed to the holders of Catalyst common stock as of January 5, 2023 under the CVR Agreement. The CVR liability was initially recorded at $5.0 million at issuance on December 26, 2022 and there was no change in the estimated fair value as of December 31, 2022.

6. Financial Instruments

Cash equivalents and investments (debt securities) which are classified as available-for-sale securities, consisted of the following *(in thousands)*:

December 31, 2022	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	$ 21,666	$ —	$ —	$ 21,666
Total financial assets	$ 21,666	$ —	$ —	$ 21,666
Classified as:				
Cash and cash equivalents				$ 21,666
Total financial assets				$ 21,666

December 31, 2021	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	$ 44,347	$ —	$ —	$ 44,347
U.S. government agency securities	2,504	—	—	2,504
Total financial assets	$ 46,851	$ —	$ —	$ 46,851
Classified as:				
Cash and cash equivalents				$ 44,347
Short-term investments				2,504
Total financial assets				$ 46,851

There have been no material realized gains or losses on available-for-sale debt securities for the periods presented. As of December 31, 2022, the Company had no available-for-sale debt securities.

7. Other Accrued Liabilities

Other accrued liabilities consisted of the following *(in thousands)*:

	Year Ended December 31,	
	2022	2021
Professional and consulting services	$ 1,417	$ 509
Manufacturing	22	1,381
Biogen	—	868
Pre-clinical	—	773
Clinical	—	361
Other	13	180
Total other accrued liabilities	$ 1,452	$ 4,072

8. Commitments and Contingencies

Business Combination Agreement

Concurrent with the F351 Asset acquisition, the Company signed a definitive agreement with GNI and other minority stockholders (“Sellers” and each a “Seller”) to acquire an indirect controlling interest in BC, a commercial-stage pharmaceutical company based in China and majority-owned subsidiary of GNI, in exchange for newly issued shares of Catalyst common stock. The closing of the Business Combination Agreement will be subject to stockholder approval at a stockholder meeting expected to be held in the third quarter of 2023 and certain customary closing conditions. If the transaction is approved by stockholders, the Company would issue at closing a total of up to 1,110,776,224 shares of Catalyst common stock for an indirect controlling interest in BC. Each Seller may elect to be issued Catalyst Convertible Preferred Stock in lieu of the Company’s common stock.

The Business Combination Agreement contains certain termination rights, including the right for Catalyst to terminate the Business Combination Agreement to enter into a definitive agreement for a superior proposal. Upon termination of the Business Combination Agreement under specified circumstances, the Company may be required to pay a termination fee of $2.0 million and either party, as the case may be, may be required to reimburse the other party for reasonable out-of-pocket fees and expenses incurred by such party in connection with the Business Combination Agreement, up to a maximum amount of $2.0 million.

Contingent Value Rights Agreement

Pursuant to the Business Combination Agreement, on December 26, 2022, Catalyst and the Rights Agent (as defined therein) executed a CVR Agreement, pursuant to which the CVR Holders received one contractual CVR issued by the Company, subject to and in accordance with the terms and conditions of the CVR Agreement, for

each share of Catalyst common stock held by such holder. Each CVR entitles the holder thereof to receive (i) certain cash payments from the net proceeds related to the disposition of the Company's legacy assets (MarzAA, DalcA, and CB 2679d-GT), (ii) 100% of the excess cash (net of all current or contingent liabilities, including transaction-related expenses) retained by the Company in excess of $1.0 million as of the closing date of the Business Combination Agreement, (iii) 100% of the amount actually received by the Company pursuant to the Vertex asset purchase agreement and (iv) 100% of the excess, by which the preapproved costs to manage, negotiate, settle and finalize certain third party claims exceed the costs actually incurred with respect to such claims. The CVRs are not transferable, except in certain limited circumstances as provided for in the CVR Agreement, will not be certificated or evidenced by any instrument, and will not be registered with the SEC or listed for trading on any exchange.

Manufacturing Agreements

The Company previously signed an agreement with AGC Biologics, Inc. ("AGC") to perform certain manufacturing services related to the Company's collaboration agreement with Biogen, which included firm work orders totaling $0.7 million. The payment obligations were fully paid off as of March 31, 2022, and Vertex assumed responsibility for further complement-related manufacturing in connection with the sale of the Company's complement portfolio to Vertex. See Note 16, *Restructuring*. During the year ended December 31, 2022, the Company terminated its manufacturing agreement with AGC for Catalyst's remaining programs and has no remaining obligations under the agreement as of December 31, 2022.

In July 2021, the Company entered into an agreement for the Company's screening and natural history of disease clinical studies related to CFI deficiency, with total payments of up to $6.5 million. During the year ended December 31, 2022, the Company terminated this agreement and incurred $0.8 million for clinical trial services incurred prior to termination and reasonable wind-down expenses. As of December 31, 2022, the Company has no remaining obligations under this agreement.

On September 16, 2021, the Company signed a Manufacturing and Research and Development Studies Agreement to support the lyophilized drug product, CB 4332. The agreement covers analytical method qualification to support good manufacturing practices ("GMP") manufacturing. The Company had firm work orders related to this agreement totaling $0.3 million. During the year ended December 31, 2022, the Company terminated this agreement and has no remaining obligations under the agreement as of December 31, 2022.

Legal Proceedings

On June 15, 2022, certain Company stockholders who beneficially held in the aggregate more than five percent (5%) of the Company's common stock filed a lawsuit in Delaware Chancery Court, captioned *JDS1, LLC v. Catalyst Biosciences, Inc*., alleging that the Company violated Section 271 of the Delaware General Corporation Law and breach of fiduciary duty in connection with the Company's asset sale to Vertex, as well as certain claims related to the alleged failure to disclose information related to the Vertex transaction. In August 2022, the lawsuit was dismissed with prejudice and the Company reimbursed JDS1, LLC for its legal and other expenses related to the litigation in the amount of $0.4 million.

COVID-19

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting the Company's employees and business operations. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national, and international markets. The COVID-19 pandemic may disrupt the Company's ability to out-license any of its remaining assets.

9. Leases

Operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term. In calculating the present value of the lease payments, the Company has elected to utilize its

incremental borrowing rate based on the original lease term and not the remaining lease term. The lease includes non-lease components (*e.g.*, common area maintenance) that are paid separately from rent based on actual costs incurred and, therefore, were not included in the right-of-use asset and lease liability but are reflected as an expense in the period incurred.

The Company leases office space for its corporate headquarters, located in South San Francisco, CA. The lease term is through April 30, 2023 and there are no stated renewal options.

In April 2021, the Company entered into a license agreement (the "License Agreement") for the use of laboratory facilities in South San Francisco, CA, for an aggregated undiscounted future payment of $1.9 million. This License Agreement commenced during the second quarter of 2021. In October 2021, the Company amended the License Agreement to extend the lease term for a period of one year. The amendment was not accounted for as a separate lease, and resulted in an adjustment to the right-of-use asset and lease liability of $0.6 million. In August 2022, the Company terminated the License Agreement.

In March 2022, the Company entered into a sublease agreement for one of its leased facilities that commenced in April 2022. Under the terms of the sublease agreement, the Company will receive $0.2 million in base lease payments over the term of the sublease, which ends in April 2023. For the year ended December 31, 2022, the Company recognized sublease income of $0.1 million.

During the year ended December 31, 2022, the Company terminated several of its lease agreements. Pursuant to the termination agreements, the Company paid $0.2 million in termination fees. The termination resulted in the derecognition of the related right-of-use assets of $1.1 million and lease liabilities of $1.0 million, and the recognition of a $0.2 million loss on lease termination for the year ended December 31, 2022, which is included in general and administrative operating expenses in the consolidated statements of operations.

For the years ended December 31, 2022 and 2021, the Company's operating lease expense was $1.7 million and $1.7 million, respectively.

The present value assumptions used in calculating the present value of the lease payments were as follows:

	December 31,	
	2022	2021
Weighted-average remaining lease term	0.3 years	1.3 years
Weighted-average discount rate	4.3%	4.8%

The maturity of the Company's operating lease liabilities as of December 31, 2022 were as follows *(in thousands):*

Year Ending December 31,	Amount
2023	$ 38
Total undiscounted lease payments	38
Less: imputed interest	—
Total operating lease liability	$ 38

Under the terms of the lease agreements, the Company is also responsible for certain variable lease payments that are not included in the measurement of the lease liability. The Company did not incur significant variable lease costs for the years ended December 31, 2022 and 2021.

Supplemental cash flow information related to operating leases was as follows *(in thousands)*:

	Year Ended December 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities	$ 1,512	$ 1,641
Prepaid cash payment for lease	—	208
Cash paid for operating leases that were included in operating cash outflows	$ 1,512	$ 1,849

10. Stock Based Compensation

2018 Omnibus Incentive Plan

In June 2018, stockholders of the Company approved the Company's 2018 Omnibus Incentive Plan (the "2018 Plan"). The 2018 Plan had previously been approved by the Company's Board of Directors (the "Board") and the Compensation Committee (the "Committee") of the Board, subject to stockholder approval. The 2018 Plan became effective on June 13, 2018. On June 9, 2021, the stockholders of the Company approved an amendment previously approved by the Board to increase the number of shares of common stock reserved for issuance under the 2018 Plan by 2,500,000 to a total of 5,300,000 shares. The amendment became effective immediately upon stockholder approval. After the option modification (as discussed below), the number of shares of common stock reserved for issuance under the 2018 Plan increased by 14,860,784 to a total of 20,160,784. As of December 31, 2022, there were 12,990,839 shares of common stock available for future grant.

Performance-Based Stock Option Grants

In June 2022, the Committee approved the issuance of an option grant to purchase 400,000 shares (1,521,568 shares after the option modification discussed below) of common stock to the Chief Executive Officer pursuant to the 2018 Plan, which will vest upon (a) the achievement of a specified performance goal and (b) the grantee's continued employment during the service period. For the year ended December 31, 2022, no expense has been recognized related to this award and no options have vested as of December 31, 2022.

Special Cash Dividend

On September 20, 2022, the Company paid a special, one-time cash dividend of $45.0 million (or $1.43 per share) to the Company's common stockholders of record as of the close of business on September 6, 2022. The Company determined, in accordance with the adjustment provision of the 2018 Plan, that the special cash dividend was unusual and non-recurring and that appropriate adjustment to the stock options to purchase shares of the Company's common stock outstanding under the 2018 Plan was required. The Company treated this adjustment as a modification to the original stock option grants because the terms of the agreements were modified in order to preserve the value of the option awards after a large non-recurring cash dividend. These options were amended to decrease the exercise price and increase the number of shares subject to the stock option on a proportionate basis. No incremental value was provided to the option holders as a result of the modification and no additional compensation cost was recorded by the Company.

The following table summarizes stock option activity under the Company's 2018 Plan and related information:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (thousands)
Outstanding — December 31, 2021	2,603,630	$ 7.70	7.46	$ —
Options granted (1)	10,270,911	1.34		
Options forfeited and cancelled (1)	(4,148,455)	4.96		
Options expired	(47,319)	13.27		
Outstanding — December 31, 2022	8,678,767	$ 1.42	7.47	$ 1,051
Exercisable — December 31, 2022	4,317,076	$ 2.38	5.94	$ —

(1) Includes options that were cancelled and re-granted as part of the option modification from the special cash dividend, as further discussed above.

The weighted-average grant date fair value of options granted during the years ended December 31, 2022 and 2021 was $0.96 and $4.00, respectively.

No options were exercised during the year ended December 31, 2022. The aggregate intrinsic value of options exercised during the year ended December 31, 2021 was $3,000.

The fair value of options vested during the years ended December 31, 2022 and 2021 was $1.9 million and $2.6 million, respectively.

Valuation Assumptions

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing formula and a single option award approach. Due to its limited relevant historical data, the Company estimated its volatility considering a number of factors including the use of the volatility of comparable public companies. The expected term of options granted under the Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is determined based on the simplified method due to the Company's limited relevant history. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option. This fair value is being amortized ratably over the requisite service periods of the awards, which is generally the vesting period.

The fair value of employee stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31,	
	2022	2021
Employee Stock Options:		
Expected term (in years)	6.02	6.00
Risk-free interest rate	3.00%	0.84%
Dividend yield	—	—
Volatility	92.58%	93.25%

Total stock-based compensation recognized was as follows *(in thousands):*

	Year Ended December 31,	
	2022	2021
Research and development	$ 330	$ 1,202
General and administrative (1)	1,012	2,203
Total stock-based compensation	$ 1,342	$ 3,405

(1) Included in general and administrative stock-based compensation for the years ended December 31, 2022 and 2021 is $30,000 and $0.3 million in expense related to 32,684 shares and 56,912 shares of common stock, respectively, issued to certain board members in lieu of their cash compensation.

As of December 31, 2022, the Company had unrecognized employee stock-based compensation expense of $1.1 million, related to unvested stock option awards, which is expected to be recognized over an estimated weighted-average period of 1.93 years.

Employee Stock Purchase Plan

In June 2018, the Company's stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"). The ESPP had previously been approved by the Board and the Compensation Committee of the Board, subject to stockholder approval which became effective as of June 13, 2018. Under the ESPP, employees meeting certain specific employment qualifications are eligible to participate and can purchase shares of common stock semi-annually on February 9th and August 9th of each year, through payroll deductions. The purchase price is 85% of the lower of the fair market value of the stock at the commencement or end of the offering period. The ESPP permits eligible employees to purchase shares of common stock through payroll deductions for up to 15% of qualified compensation.

The Company's ESPP is subject to an Evergreen provision which shares may be added to the pool as needed. As of December 31, 2022, a total of 359,545 shares of common stock may be granted in accordance with the terms of the ESPP.

For the year ended December 31, 2022, a total of 47,662 shares of common stock for $20,000 have been issued to employees participating in the two ESPP purchases during 2022 and 187,807 shares are available for issuance under the ESPP as of December 31, 2022.

Stock-based compensation expense for the ESPP was not significant and $0.1 million for the years ended December 31, 2022 and 2021, respectively, and is included in total stock-based compensation recognized.

11. Income Taxes

The components of the provision for income taxes for the years ended December 31, 2022 and 2021 consist of the following:

	Year Ended December 31,	
	2022	2021
Current tax provision:		
Federal	$ 341	$ —
State	7	—
Total tax provision	$ 348	**$ —**

The reconciliation of the federal statutory income tax rate to the Company's effective tax rate for the years ended December 31, 2022 and 2021 are as follows:

	Year Ended December 31,	
	2022	2021
Tax at statutory federal rate	-21.00%	-21.00%
State Tax (benefit)—net of federal benefit	-0.01%	0.00%
Permanent differences	1.00%	0.35%
Tax credits	-42.08%	-5.86%
Derecognition due to Sec. 382 and 383 limitations	139.00%	0.00%
Change in valuation allowance	-69.24%	26.26%
Fixed assets other adjustment	-1.19%	0.00%
Other	-2.07%	0.25%
Effective tax rate	4.41%	0.00%

Significant components of the Company's deferred tax assets as of December 31, 2022 and 2021 consist of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Deferred tax assets:		
Accruals and reserves	$ 1,273	$ 1,000
Net operating loss carry forwards	40,770	47,541
Tax credit carry forwards	4,463	12,939
Fixed and intangible assets	9,510	3
Valuation allowance	(56,016)	(61,483)
Net deferred tax assets:	$ —	$ —

Based on the available objective evidence at December 31, 2022, the Company does not believe it is more likely than not that the net deferred tax assets will be realizable. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets at December 31, 2022 and 2021. The net valuation allowance decreased by approximately $5.5 million and increased by approximately $23.1 million during the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, after consideration of certain limitations (see below), the Company had approximately $194.1 million federal and $3.6 million state net operating loss carryforwards ("NOL") available to reduce future taxable income which, if unused, will begin to expire in 2037 for federal and 2032 for state tax purposes. The federal net operating loss carryforward includes $192.4 million that have an indefinite life.

As of December 31, 2022, the Company also had tax credit carry forwards available to offset future tax liabilities of approximately $8,500 for federal and $7.5 million for state. If unused, the federal credit will begin to expire in 2042 and the state tax credit does not expire.

If the Company experiences a greater than 50 percent aggregate change in ownership over a three-year period (a Section 382 ownership change), utilization of its pre-change NOL carryforwards are subject to annual limitation under Section 382 of the Internal Revenue Code (California has similar provisions). The annual limitation is determined by multiplying the value of the Company's stock at the time of such ownership change by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. The Company determined that ownership changes occurred on December 31, 2007, August 20, 2015, April 13, 2017, February 15, 2018, February 18, 2020, and December 26, 2022. Approximately $156.5 million and $75.2 million of the NOLs will expire unutilized for federal and California purposes, respectively. The Company has derecognized NOL related deferred tax assets in the tax affected amounts of $32.9 million and $0 for federal and California purposes, respectively through the year ended December 31, 2022.

All of the federal R&D credits could expire unutilized, whereas none of the California R&D credits are subject to expiration. Approximately $26.1 million of gross federal R&D credit-related deferred tax assets were derecognized due to the Section 383 limitation. The ability of the Company to use its remaining NOL and carryforwards may be further limited if the Company experiences a Section 382 ownership change as a result of future changes in its stock ownership.

On June 29, 2020, the California Governor signed Assembly Bill 85 ("A.B. 85"), which now becomes California law. A.B. 85, which includes several tax measures, provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5 million of tax per year. Generally, A.B. 85 suspends the use of net operating losses for taxable years 2020, 2021, and 2022 for taxpayers with taxable income of $1 million or more. Since the Company is not expected to generate California source taxable income of more than $1 million, no material impact is anticipated at this time.

Accounting for Uncertainty in Income Taxes

The Company only recognizes tax benefits if it is more likely than not that they will be sustained upon audit by the relevant tax authority based upon their technical merits. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The Company had approximately $1.9 million and $4.7 million of unrecognized tax benefits as of December 31, 2022 and 2021, respectively. As the Company has a full valuation allowance on its deferred tax assets, the unrecognized tax benefits have reduced the deferred tax assets and the valuation allowance in the same amount. The Company does not expect the amount of unrecognized tax benefits to materially change in the next twelve months.

A reconciliation of the beginning and ending balance of the unrecognized tax benefits is as follows *(in thousands)*:

Beginning Balance at January 1, 2021	**$**	**2,955**
Increase/(Decrease) of unrecognized tax benefits taken in prior years		—
Increase/(Decrease) of unrecognized tax benefits related to current year		1,749
Ending Balance at December 31, 2021	**$**	**4,704**
Increase/(Decrease) of unrecognized tax benefits taken in prior years		(2,841)
Increase/(Decrease) of unrecognized tax benefits related to current year		20
Ending Balance at December 31, 2022	**$**	**1,883**

Interest and penalties related to unrecognized tax benefits would be included as income tax expense in the Company's consolidated statements of operations. As of December 31, 2022 and 2021, the Company had not recognized any tax-related penalties or interest in its consolidated financial statements.

The Company files income tax returns in the United States federal and California, with a new filing in Florida for tax year 2022. The Company filed final returns in 2021 in Kansas, Missouri and New Jersey state jurisdictions. The Company is not currently under examination by income tax authorities in federal, state or other jurisdictions. As of December 31, 2022 and 2021, the Company had no uncertain tax positions which affected its financial position as its results of operations or its cash flow, and will continue to evaluate for uncertain tax positions in the future. The Company is subject to United States federal and state income tax examinations by authorities for all tax years due to accumulated net operating losses that are being carried forward for tax purposes.

12. Collaborations

Mosaic

In October 2017, the Company entered into a strategic research collaboration with Mosaic to develop intravitreal anti-complement factor 3 (C3) products for the treatment of dry Age-related Macular Degeneration (AMD) and other retinal diseases. The Company subsequently amended this agreement in December 2018, December 2019 and May 2020.

Under the as amended Mosaic collaboration agreement, Mosaic is eligible to receive up to $4.0 million in potential future milestone payments related to regulatory and clinical development events for CB 2782-PEG and an additional anti-complement product candidate in lieu of the Company's prior obligations to pay Mosaic a double-digit percentage of funds the Company receives from Biogen or any other amounts the Company receives related to sublicense fees, research and development payments, or any other research, regulatory, clinical or commercial milestones and royalties on any other development candidates.

As a result of the sale of the Company's complement portfolio, including CB 2782-PEG and other assets, to Vertex in May 2022, the Mosaic collaboration agreement was transferred to Vertex. See Note 16, *Restructuring*.

ISU Abxis

In December 2018, the Company entered into an amended and restated license agreement with ISU Abxis (the "A&R ISU Abxis Agreement"). Under the A&R ISU Abxis Agreement, ISU Abxis will receive commercialization rights in South Korea to the Company's engineered Factor IX dalcinonacog alfa - DalcA and the Company will receive clinical development and commercialization rights in the rest of world (excluding South Korea) and manufacturing development and manufacturing rights worldwide (including South Korea). The A&R ISU Abxis Agreement provides for a low single-digit royalty payment to ISU Abxis, on a country-by-country basis, for net product sales of DalcA by the Company or its affiliates in each country other than South Korea. Pursuant to the A&R ISU Abxis Agreement, the Company will also pay up to an aggregate of $19.5 million in milestone payments to ISU Abxis, including $2.5 million in regulatory and development milestone payments and up to $17.0 million in commercial milestone payments, if the applicable milestones are met. As of December 31, 2022, no milestones have been met.

As a result of the sale of the Company's rare bleeding disorders programs, including DalcA and other assets, to GCBP in February 2023, the A&R ISU Abxis Agreement was transferred to GCBP. See Note 17, *Subsequent Events.*

Biogen

On December 18, 2019, the Company and Biogen entered into a License and Collaboration Agreement (the "Biogen Agreement"), under which the Company granted Biogen a worldwide, royalty-bearing, exclusive, with the right to sublicense, license ("Exclusive License") to develop and commercialize CB 2782-PEG and other anti-C3 proteases for potential treatment of dry AMD and other disorders. Pursuant to the Biogen Agreement, the Company performed certain pre-clinical and manufacturing activities ("Research Services"), and Biogen was solely responsible for funding the pre-clinical and manufacturing activities and performing IND-enabling activities, worldwide clinical development, and commercialization.

Under the terms of the Biogen Agreement, the Company received an up-front payment for the transfer of the Exclusive License (inclusive of certain know-how) of $15.0 million in January 2020. The Company was eligible to receive development milestones and sales milestones of up to $340.0 million. In addition, the Company was eligible to receive royalties in the range of single-digit to low double-digit percentage rates of annual net sales on a product-by-product and country-by-country basis. The Company also received reimbursements for costs associated with the performance of the Research Services.

The Company determined that the performance obligations under the Biogen Agreement were the Exclusive License and the Research Services. For the Exclusive License, the Company used the residual approach in determining the standalone selling price, or SSP, which includes the upfront payments, milestones and royalties. For the Research Services, the Company used the historical pricing approach for determining the SSP, which includes the reimbursement of personnel and out-of-pocket costs.

In March 2022, the Company received written notice from Biogen declaring intent to terminate the Biogen Agreement which was effective as of May 2022. As a result of the termination, Biogen no longer has the Exclusive License to develop, manufacture and commercialize CB 2782-PEG and other anti-C3 proteases for potential treatment of dry AMD and other disorders. In March 2022, Biogen returned full rights to CB 2782-PEG.

In June 2022, Biogen and the Company reached an agreement to resolve the outstanding obligations and monetary disputes between the parties. The Company agreed to forgive approximately $0.6 million of accounts receivable due from Biogen and to pay Biogen $10,000 in cash. This resulted in the Company recognizing a $0.6 million settlement expense for the year ended December 31, 2022, which is included in general and administrative operating expenses in the consolidated statements of operations.

For the years ended December 31, 2022 and 2021, the Company recognized no license revenue from the Biogen Agreement.

For the years ended December 31, 2022 and 2021, the Company recognized $0.8 million and $7.3 million in collaboration revenue for reimbursable out-of-pocket and personnel costs incurred related to Research Services.

For the year ended December 31, 2022, the Company recognized $0.2 million in collaboration revenue from the beginning of period deferred revenue balance.

13. Interest and Other Income (Expense), Net

The following table shows the detail of interest and other income (expense), net as follows *(in thousands):*

	Year Ended December 31,	
	2022	2021
Interest income	$ 537	$ 39
Gain from extinguishment of liability	180	—
Other	—	(78)
Total interest and other income (expense), net	$ 717	$ (39)

14. Stockholders' Equity

Common Stock

Under the Company's amended and restated certificate of incorporation, the Company has 100,000,000 shares of common stock authorized for issuance with a $0.001 par value per share. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of a majority of the Company's stock who are entitled to vote. Each share of common stock is entitled to one vote. The holders of common stock are entitled to receive dividends when and as declared or paid by the Board.

The Company had 0 and 85 issued and outstanding common stock warrants as of December 31, 2022 and 2021, respectively, with a weighted-average exercise price of $392.70. The warrants expired in August 2022.

2021 ATM Program

On October 15, 2021, the Company entered into an Equity Distribution Agreement (the "ATM Agreement") with Piper Sandler, as sales agent, pursuant to which the Company may offer and sell, from time to time, through Piper Sandler, shares of the Company's common stock, par value of $0.001 per share, with aggregate gross sales proceeds of up to $50.0 million through the ATM Program. The Company will pay Piper Sandler a commission of 3.0% of the gross proceeds of any shares sold. The Company also agreed to reimburse Piper Sandler for certain expenses incurred in connection with its services under the ATM Agreement, including up to $50,000 for legal expenses in connection with the establishment of the ATM Program.

Sales of shares of common stock under the ATM Program will be made pursuant to the registration statement on Form S-3 (File No. 333-253874), which was declared effective by the SEC on May 3, 2021, and a related prospectus supplement file with the SEC on October 15, 2021. For the years ended December 31, 2022 and 2021, no shares of common stock were sold under the ATM Program.

Redeemable Convertible Preferred Stock

The Company is authorized to issue 5,000,000 shares of preferred stock with a par value of $0.001 per share under its restated certificate of incorporation. Under the Catalyst Convertible Preferred Stock Certificate of Designation, the Company has designated 123,418 shares to be Catalyst Convertible Preferred Stock and is authorized to issue up to 12,340 shares of Catalyst Convertible Preferred Stock pursuant to the terms of the F351 Agreement and up to 111,078 shares of Catalyst Convertible Preferred stock pursuant to the terms of the Business Combination Agreement. As of December 31, 2022, the Company has 12,340 shares of Catalyst Convertible Preferred Stock issued and outstanding. Refer to Note 1, *Nature of Operations*, regarding the Company's issuance of Catalyst Convertible Preferred Stock in December 2022.

Subject to stockholder approval, each share of Catalyst Convertible Preferred Stock issued under the F351 Agreement is convertible into 10,000 shares of common stock. The Company is required to hold a stockholders' meeting to request the approval of the conversion of the Catalyst Convertible Preferred Stock into shares of common stock in accordance with Nasdaq Listing Rule 5635(a) (the "Conversion Proposal"). The Company expects to hold its 2023 Annual Meeting of Stockholders in the third quarter of 2023 and will include the following matters as proposals to be voted on at the meeting: (i) the Conversion Proposal and (ii) if necessary or appropriate, the approval of an amendment to the Company's certificate of incorporation to authorize sufficient shares of common stock for the conversion of the Catalyst Convertible Preferred Stock issued pursuant to the F351 Agreement.

If the Company's stockholders do not approve the conversion of the Catalyst Convertible Preferred Stock by June 26, 2023 (which has been extended to September 30, 2023, see Note 17, *Subsequent Events*), then the holders of the Catalyst Convertible Preferred Stock are entitled to require the Company to make cash payments at a price per share equal to the fair value of undelivered shares of common stock, defined as the last reported closing price of the Company's common stock on the trading day on which notice of conversion is delivered to the Company. Using the closing price on March 24, 2023 of $0.21, if all the currently outstanding Catalyst Convertible Preferred Stock was redeemed for cash, the Company would be required to make a payment of approximately $25.7 million. The Company has insufficient liquidity to make such a payment, if required.

Holders of Catalyst Convertible Preferred Stock are entitled to receive dividends on shares of Catalyst Convertible Preferred Stock equal, on an as-if-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of the Company's common stock. Except as otherwise required by law, the Catalyst Convertible Preferred Stock does not have voting rights. However, as long as any shares of Catalyst Convertible Preferred Stock are outstanding, the Company may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Catalyst Convertible Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Catalyst Convertible Preferred Stock or alter or amend this Certificate of Designation that authorized the Catalyst Convertible Preferred Stock, amend or repeal any provision of or add any provision to, the Certificate of Incorporation or bylaws of the Company, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Catalyst Convertible Preferred Stock, (ii) issue further shares of Catalyst Convertible Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Catalyst Convertible Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing. Additionally, the approval of the holders of a majority of the Catalyst Convertible Preferred Stock is required for certain change of control transactions, provided that this approval right will terminate upon stockholder approval of the Conversion Proposal. The Catalyst Convertible Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company.

Following stockholder approval of the Conversion Proposal, each share of Catalyst Convertible Preferred Stock is convertible into shares of common stock at any time at the option of the holder thereof, into 10,000 shares of the Company's common stock, subject to certain beneficial ownership limitations, including that a holder of Catalyst Convertible Preferred Stock is prohibited from converting shares of Catalyst Convertible Preferred Stock into shares of the Company's common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (to be initially set at 9.99% and thereafter adjustable by the holder to a number between 4.99% and 19.99%) of the total number of shares of the Company's common stock issued and outstanding immediately after giving effect to such conversion.

The Catalyst Convertible Preferred Stock is classified as temporary equity on the consolidated balance sheet because if conversion to common stock is not approved by the shareholders, the Catalyst Convertible Preferred Stock would be redeemable at the option of the holders for cash equal to the closing price of the common stock on last trading day prior to the holder's redemption request. The Catalyst Convertible Preferred Stock is recorded at its relative fair value on the date of issuance (i.e., the closing date of the F351 Asset acquisition) and the Company has not adjusted the carrying value to its redemption value since the Catalyst Convertible Preferred Stock is not currently redeemable, and it is not probable that it will become redeemable in the future at the balance sheet date. Subsequent adjustments to the carrying value will be made only when it becomes probable that such redemption will occur.

15. Net Loss per Share Attributable to Common Stockholders

Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	Year Ended December 31,	
	2022	2021
Options to purchase common stock	8,678,767	2,603,630
Redeemable convertible preferred stock (1)	123,400,000	—
Common stock warrants	—	85
Total	132,078,767	2,603,715

(1) Shown as common stock equivalents

16. Restructuring

In November 2021, the Board approved a restructuring of its business based on its decision to stop the clinical development of MarzAA and focus solely on its complement programs and protease medicines platform. The restructuring included a reduction-in-force whereby approximately 35% of employees were terminated. During the year ended December 31, 2021, the Company recorded charges of $0.4 million related to one-time severance costs and related expenses in connection with the workforce reduction, and charges of $3.8 million related to the write-off of prepaid manufacturing costs that will no longer be used for the clinical development of MarzAA. As of December 31, 2021, the remaining restructuring liability was $0.2 million, which the Company paid during the second quarter of 2022.

In March 2022, the Board approved a further reduction of its workforce as part of its restructuring plan whereby 22 full-time employees were terminated. Following this reduction, the Company had five full-time employees remaining. During the quarter ended March 31, 2022, the Company recorded additional charges of $1.0 million for severance and other costs related to the reduction-in-force, recognized as an operating expense within the consolidated statements of operations, which the Company paid during the second quarter of 2022.

The following table summarizes restructuring charges recorded in each component of operating expenses in the Company's consolidated statements of operations (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	$ 609	$ 4,025
General and administrative	402	143
Total restructuring charges	$ 1,011	$ 4,168

Sale of Assets

During the year ended December 31, 2022, the Company entered into sales agreements, pursuant to which the Company sold various lab equipment, consumables, and furniture and fixtures for total consideration of $0.5 million. The Company recorded a loss on disposal of $0.2 million, which is included in gain on disposal of assets, net in the consolidated statements of operations.

In May 2022, the Company entered into an asset purchase agreement with Vertex, pursuant to which Vertex purchased the Company's complement portfolio, including CB 2782-PEG and CB 4332, as well as its complement-related intellectual property including the ProTUNE™ and ImmunoTUNE™ platforms for $60.0 million in cash consideration. Cash of $55.0 million was received upfront in May 2022 and the remaining $5.0 million will be paid one year after the closing upon satisfaction of certain post-closing indemnification obligations. The hold-back amount is recorded within accounts and other receivables on the consolidated balance sheet. There were no carrying amounts associated with the intellectual property sold to Vertex, and,

therefore, the Company recorded a gain of $57.4 million related to the disposal, net of $2.6 million of transaction costs, which is included in gain on disposal of assets, net in the consolidated statements of operations.

17. Subsequent Events

Payment of Dividend

On January 12, 2023, the Company paid a one-time cash dividend of $0.24 per share, or approximately $7.6 million, to the Company's common stockholders of record as of close of business on January 5, 2023. GNI common stockholders were not entitled to such dividend payment.

Sale of Assets

On February 27, 2023, Catalyst entered into an asset purchase agreement with GC Biopharma Corp. ("GCBP"), pursuant to which GCBP acquired the Company's legacy rare bleeding disorders programs including MarzAA, DalcA and CB-2679d-GT for $6.0 million in cash consideration. Cash of $1.0 million was received upfront in February 2023 and the remaining $5.0 million will be paid two years after the closing upon satisfaction of certain post-closing indemnification obligations. In March 2023, the Company distributed the net cash proceeds received upfront of $0.2 million to the CVR Holders. Once received, the remaining net proceeds from the transaction will be distributed to the CVR Holders.

Silicon Valley Bank Closure

As of March 10, 2023, the Company maintained two accounts at Silicon Valley Bank ("SVB") holding cash deposits of approximately $9.0 million. On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation ("FDIC") was appointed receiver. The FDIC initially announced that all insured depositors will have full access to their insured deposits no later than, March 13, 2023, with uninsured depositors receiving an advance dividend receivership certificate for their uninsured funds. On March 12, 2023, the U.S. Treasury Department, the Federal Reserve and the FDIC jointly announced enabling actions that fully protect all SVB depositors' insured and uninsured deposits, and that such depositors would have access to all of their funds starting March 13, 2023. On March 13, 2023, the Company was able to access its full deposits with SVB.

F351 Agreement Amendment

In March 2023, the Company amended the F351 Agreement and the Catalyst Convertible Preferred Stock Certificate of Designation to extend the deadline for the cash settlement of the Catalyst Convertible Preferred Stock to September 30, 2023. Under the amended terms, if the Company's stockholders do not approve the conversion of the Catalyst Convertible Preferred Stock by September 30, 2023, then the Catalyst Convertible Preferred Stock would be redeemable at the option of the holders for cash equal to the closing price of the common stock on last trading day prior to the holder's redemption request.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

Management, with the participation of our Chief Executive Officer and our Interim Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits 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 provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. 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 cost-benefit relationship of possible controls and procedures. Based on their evaluation of our disclosure controls and procedures as of December 31, 2022, our Chief Executive Officer and Interim Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Remediation of Previously Reported Material Weaknesses

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls. As previously reported on Form 10-K for the period ended December 31, 2021 filed with the SEC on March 31, 2022 and in our subsequent Form 10-Q reports for the periods ending March 31, June 30 and September 30, 2022, management identified a material weakness in internal control over financial reporting during the audit of our consolidated financial statements for the year ended December 31, 2021. The material weakness that was previously identified related to the following:

- We did not design and maintain effective controls related to the review of certain contracts, including the proper application of GAAP. Specifically, we did not design and maintain controls to properly review the retention bonuses granted to our employees in November 2021 after our reduction in workforce to assess the appropriate accounting treatment under GAAP.

Management has been actively engaged in remediating the above-described material weakness. During the year ended December 31, 2022, we implemented measures designed to improve our internal control over financial reporting to remediate the material weakness, including:

- Enhancing controls supporting the employment contracts; and
- Providing increased attention and review of the employment contracts by personnel with U.S. GAAP knowledge and experience.

Management has concluded that the actions taken to strengthen our internal control over financial reporting, as well as the results of our testing over the design and operating effectiveness of these controls remediated the previously identified material weakness as of December 31, 2022. However, 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 applicable policies, processes and documentation requirements may deteriorate.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed 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. 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 and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under that framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Management's Annual Report on Internal Control Over Financial Reporting

Except as described above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act) during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

Item 9C. DISCLOSURES REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this Item is incorporated by reference to the information set forth in the sections titled “Information About Our Board of Directors” and “Information About Our Executive Officers Who Are Not Directors,” “Corporate Governance,” “Corporate Governance – Code of Business Conduct and Ethics,” “Delinquent Section 16(a) Reports,” “Corporate Governance – Committees of the Board of Directors – Nominating and Corporate Governance Committee,” “Corporate Governance – Committees of the Board of Directors – Audit Committee” and “Corporate Governance – Committees of the Board of Directors – Compensation Committee” in our definitive proxy statement to be filed with the SEC on Schedule 14A in connection with our 2023 Annual Meeting of Shareholders, or the Proxy Statement, which is expected to be filed not later than 120 days after December 31, 2022.

Item 11. EXECUTIVE COMPENSATION

Information required by this Item is incorporated by reference to the information set forth in the sections titled “Executive Compensation,” “Director Compensation” and “Committees of the Board of Directors — Compensation Committee Interlocks and Insider Participation” in the Proxy Statement and is incorporated herein by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information required by this Item is included in the sections titled “Securities Authorized For Issuance Under Equity Compensation Plans” and “Security Ownership of Certain Beneficial Owners and Management” in the Proxy Statement and is incorporated herein by reference.

Item 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information required by this Item is included in the sections titled “Corporate Governance – Board of Directors Independence” and “Transactions With Related Persons” in the Proxy Statement and is incorporated herein by reference.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by this Item is included in the sections titled “Independent Registered Public Accounting Firm Fees and Services” in the Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Consolidated Financial Statements

   See Index to Consolidated Financial Statements at Part II, Item 8 Financial Statements and Supplementary Data, herein.

2. Consolidated Financial Statement Schedules

   All schedules are omitted because they are not applicable or the required information is shown under Item 8. “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

3. See LIST OF EXHIBITS

(b) See LIST OF EXHIBITS

Item 16. FORM 10-K SUMMARY

None.

LIST OF EXHIBITS

Exhibit No.	Exhibit title	Incorporated by reference				Filed or Furnished herewith
		Form	File No.	Exhibit No.	Filing Date	
2.1(a)	Agreement and Plan of Merger dated as of March 5, 2015, by and among Targacept, Catalyst Biosciences, Inc. and Talos Merger Sub, Inc.	8-K	000-51173	2.1	Mar. 6, 2015	
2.1(b)	Amendment No. 1 to Agreement and Plan of Merger by and among Targacept, Talos Merger Sub, Inc., and Catalyst dated May 6, 2015.	8-K	000-51173	10.1	May 12, 2015	
2.1(c)	Amendment No. 2 to Agreement and Plan of Merger by and among Targacept, Talos Merger Sub, Inc., and Catalyst dated May 13, 2015.	8-K	000-51173	10.1	May 14, 2015	
3.1	Fourth Amended and Restated Certificate of Incorporation of the Company.	S-8	333-133881	4.1	May 8, 2006	
3.2	Certificate of Amendment to Fourth the Amended and Restated Certificate of Incorporation of the Company.	8-K	000-51173	3.1	Aug. 20, 2015	
3.3	Second Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Company.	8-K	000-51173	3.1	Feb. 10, 2017	
3.4	Bylaws of the Company, as amended.	8-K	000-51173	3.1	Jun. 16, 2020	
3.5	Certificate of Designation of Preferences, Rights and Limitations, filed with the Delaware Secretary of State on April 10, 2017, with respect to the Series A Preferred Stock.	8-K	000-51173	3.1	Apr. 13, 2017	
4.1	Description of Securities.	10-K	000-51173	4.1	Feb. 20, 2020	
4.2	Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to Silicon Valley Bank on March 3, 2005.	10-K	000-51173	4.3	Mar. 9, 2016	
4.3	Form of Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to purchasers of convertible promissory notes.	10-K	000-51173	4.5	Mar. 9, 2016	
10.1**	Catalyst Biosciences, Inc. (formerly Targacept, Inc.) 2015 Stock Incentive Plan (as Amended and Restated Effective June 9, 2016).	DEF 14A	000-51173	Appendix A	Apr. 25, 2016	
10.2**	Catalyst Biosciences, Inc. 2016 Inducement Stock Incentive Plan.	8-K	000-51173	10.1	Apr. 20, 2016	
10.3**	Catalyst's 2004 Stock Plan.	S-4	333-204423	10.31(a)	May 22, 2015	

Exhibit No.	Exhibit title	Incorporated by reference				Filed or Furnished herewith
		Form	File No.	Exhibit No.	Filing Date	
10.4**	Form of Incentive Stock Option Award Notice.	8-K	000-51173	10.1	July 14, 2017	
10.5**	Form of Non-qualified Stock Option Award Notice.	8-K	000-51173	10.2	July 14, 2017	
10.6**	Catalyst Biosciences, Inc. 2018 Omnibus Incentive Plan.	DEF 14A	000-51173	Appendix A	May 1, 2020	
10.7**	Catalyst Biosciences, Inc. 2018 Employee Stock Purchase Plan.	DEF 14A	000-51173	Appendix B	May 11, 2018	
10.8**	Form of Stock Option Award Agreement.	10-K	000-51173	10.8	Mar. 31, 2022	
10.9	License Agreement, dated as of April 15, 2021, by and between SL 2T, LLC and Catalyst Biosciences, Inc.	10-Q	000-51173	10.1	Aug. 5, 2021	
10.10**	Amended and Restated Employment Agreement, dated as of August 28, 2018, by and between Catalyst Biosciences, Inc. and Dr. Nassim Usman, Ph.D.	8-K	000-51173	10.1	Aug. 31, 2018	
10.11++	Clinical Supply Agreement, effective as of October 4, 2019, by and between Catalyst Biosciences, Inc. and Catalent Indiana, LLC.	8-K	000-51173	10.1	Oct. 15, 2019	
10.12++	Amended and Restated License Agreement, dated December 17, 2018, by and between Catalyst Biosciences, Inc. and ISU Abxis.	10-K/A	000-51173	10.16	Apr. 29, 2019	
10.13+	Development and Manufacturing Services Agreement, by and between CMC ICOS Biologics, Inc. and Biosciences, Inc., dated as of May 20, 2016.	10-Q	000-51173	10.1	Aug. 4, 2016	
10.14(a)	Lease Agreement, dated November 8, 2017 by and between BXP 611 Gateway Center, LP and Catalyst Biosciences, Inc..	8-K	000-51173	10.1	Nov. 17, 2017	
10.14(b)	First Amendment to Office Lease, dated as of August 9, 2018, by and between BXP 611 Gateway Center, LP and Catalyst Biosciences, Inc.	8-K	000-51173	10.1	Aug. 15, 2018	
10.15++	License and Collaboration Agreement, dated December 18, 2019, by and between Biogen International GMBH and Catalyst Biosciences, Inc.	10-K	000-51173	10.17	Feb. 20, 2020	
10.16	Description of Annual Cash Incentive Program.	10-K	000-51173	10.20	Feb. 20, 2020	

Exhibit No.	Exhibit title	Incorporated by reference				Filed or Furnished herewith
		Form	File No.	Exhibit No.	Filing Date	
10.17**	Form of Indemnification Agreement between the Company and each of its directors and members of executive management.	10-K	000-51173	10.14	Mar. 8, 2017	
10.18	Second Amendment to Office Lease, dated July 17, 2020, by and between 611 Gateway Center, L.P. and Catalyst Biosciences, Inc.	10-Q	000-51173	10.1	Nov. 5, 2020	
21.1	List of subsidiaries of Catalyst Biosciences, Inc.	10-K	000-51173	21.1	Mar. 9, 2016	
23.1	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (included as part of the signature page hereto).					X
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of the Interim Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2	Certification of the Interim Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X

Exhibit No.	Exhibit title	Incorporated by reference				Filed or Furnished herewith
		Form	File No.	Exhibit No.	Filing Date	
101	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2022, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets as of December 31, 2022 and December 31, 2021; (ii) the Consolidated Statement of Operations for the years ended December 31, 2022 and 2021; (iii) the Consolidated Statements of Comprehensive Loss for the years ended December 31, 2022 and 2021; (iv) the Consolidated Statements of Stockholders' Equity as of December 31, 2022; (v) the Consolidated Statements of Cash Flows for the twelve months ended December 31, 2022 and 2021; and (vi) the Notes to the Consolidated Financial Statements.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					

** Denotes management contract, compensatory plan or arrangement.

+ Confidential treatment has been granted with respect to certain portions of this Exhibit, which portions have been omitted and filed separately with the SEC as part of an application for confidential treatment.

++ Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

CATALYST BIOSCIENCES, INC

By: /s/ Nassim Usman, Ph.D.

Nassim Usman, Ph.D.
President and Chief Executive Officer

Date: March 30, 2023

CATALYST BIOSCIENCES, INC.

By: /s/ Seline Miller

Seline Miller
Interim Chief Financial Officer

Date: March 30, 2023

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Nassim Usman and Seline Miller, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all 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, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Nassim Usman, Ph.D. **Nassim Usman, Ph.D.**	President and Chief Executive Officer (*Principal Executive Officer*)	March 30, 2023
/s/ Seline Miller **Seline Miller**	Interim Chief Financial Officer (Interim Financial and Principal Accounting Officer)	March 30, 2023
/s/ Ying Luo, Ph.D. **Ying Luo, Ph.D.**	Chairman of the Board of Directors	March 30, 2023
/s/ Thomas Eastling **Thomas Eastling**	Director	March 30, 2023
/s/ Andrea Hunt **Andrea Hunt**	Director	March 30, 2023
/s/ Augustine Lawlor **Augustine Lawlor**	Director	March 30, 2023

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Catalyst Biosciences, Inc. on Form S-8 (Nos. 333-133881, 333-133882, 333-160331, 333-185888, 333-189143, 333-206523, 333-206526, 333-212345, 333-219301, 333-225902, 333-239712, and 333-264027), and Form S-3 (Nos. 333-228970 and 333-253874) of our report dated March 30, 2023, on our audits of the financial statements as of December 31, 2022 and 2021, and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 30, 2023. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 30, 2023

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nassim Usman, certify that:

1. I have reviewed this Annual Report on Form 10-K of Catalyst Biosciences, Inc. for the period ended December 31, 2022;

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(s) 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(s) 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 30, 2023

/s/ Nassim Usman, Ph.D.

Nassim Usman, Ph.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Seline Miller, certify that:

1. I have reviewed this Annual Report on Form 10-K of Catalyst Biosciences, Inc. for the period ended December 31, 2022;

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(s) 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(s) 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 30, 2023

/s/ Seline Miller

Seline Miller

Interim Chief Financial Officer (Interim Financial and Principal 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 the Annual Report on Form 10-K of Catalyst Biosciences, Inc. (the "Company") for the period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nassim Usman, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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 30, 2023

/s/ Nassim Usman, Ph.D.

Nassim Usman, Ph.D.
President and Chief 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 the Annual Report on Form 10-K of Catalyst Biosciences, Inc. (the "Company") for the period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Seline Miller, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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 30, 2023

/s/ Seline Miller

Seline Miller
Interim Chief Financial Officer (Interim Financial and Principal Accounting Officer)