MOSSADAMS

Under the Microscope

An Analysis of SEC Comment Letter Trends
Among Middle-Market and Pre-IPO Life Sciences Companies

2021-2022

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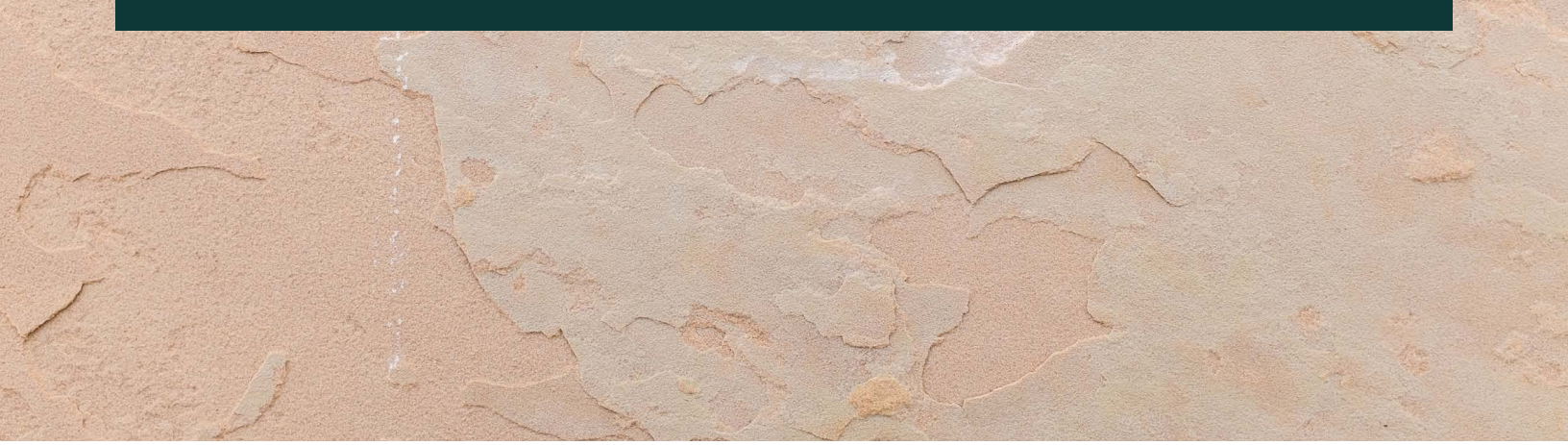


INDUSTRY OVERVIEW

After a record-breaking 2021, the initial public offering (IPO) market faced some headwinds entering 2022. Deal activity slowed due to macro-instability and subdued performance of newly public companies, but market sentiment remained largely upbeat.

As the industry tackles external volatility and continues expanding on increased demand for medical solutions, investors and companies are looking for the IPO market to rebound in 2023.

PERFORMANCE RECAP

More than 114 life sciences companies filed traditional IPOs in 2021, according to Fenwick & West's IPO market review with over 66 life sciences IPOs in the first half of the year, then slowed to 48 in the second half. This number excludes de-SPAC (special purpose acquisition company) mergers, which trended in the equity capital markets landscape last year.

As of late March 2022, of the 21 IPOs recorded, only a handful were in the technology or life sciences sectors.

Many factors contributed to this slowdown. 2021's deal market proved overly enthusiastic, especially in the biotechnology space. One of the factors forcing a return to previous levels was the busy deal market in 2021, especially in biotech. Those IPOs were numerous early on due to renewed interest in pharmaceutical innovation and vaccine drives, and many early-stage valuations were built solely on futuristic promises.

Since 2020, investors were interested in breakthrough therapies, including those in early stages. When those companies weren't able to deliver product advancement into clinical or even preclinical phases in certain cases, share prices dropped dramatically.

The market quieted in 2022. At the same time, the macroenvironment played a role. Global volatility stemming from the conflict in Ukraine and rising interest rates gave 2022 a bumpy beginning.

COVID-19 proved to be a double-edged sword for life sciences. While excitement for new drug development accelerated, the supply-side disruptions widely interrupted clinical trials for the past two years. Raw materials weren't delivered to production facilities, patients and medical providers fell sick, and sites closed for pandemic precautions.

Despite this, investor confidence is steadfast and the market is expected to rebound. A focus shift from addressing immediate needs related to COVID-19

back to health care advancement is underway. Companies are designing solutions for unmet needs, together with innovations that arose and accelerated because of COVID-19, such as leveraging and prioritizing telemedicine, and creating smart wearable health devices and related health care software.

The next question is how steady the market will remain despite bouts of external volatility and uncertainty over valuations, affecting whether IPO deals close.

KEY INDUSTRY TRENDS

As the life sciences industry continues to revolutionize on a global scale and integrate technological accelerators across the value spectrum, a new business ecosystem is in the making. Such technological accelerators include artificial intelligence (AI), blockchain, cloud computing, and internet of things (IoT).

The pace of technological development is unprecedented, and the digital health field—producing mobile health and wearable devices—grows. This data-driven industry also invites an equally data-driven regulatory scope, with a host of new regulations set to monitor both US and international collaborations, as well as issues related to data privacy and cybersecurity.

Frameworks that monitor the use of accelerators such as artificial intelligence and blockchain also face scrutiny.

As industry players race toward innovative solutions, regulators explore ways to ensure products are safe, effective, affordable, and accessible. The nature of many emerging products requires innovative licensing and collaboration agreements. These agreements can lead to intellectual property and contractual compliance issues.

Among these trends, the Food and Drug Administration's (FDA) new intended use rule is a recent development for the US market. The widened scope can make drug and medical device manufacturers face increased potential exposure in off-label promotion cases.

Four key aspects of expected growth in life sciences are:

- Innovation
- Technology
- Sustainability
- Compliance

A well-defined developmental plan will be critical for any activity, from designing new drugs to building technological pathways. Any documents or procedures, from the fine print in licensing agreements to expansions of production facilities across foreign locations, must meet standards and be prepared for inspection.

Attention paid to environmental, social, and governance (ESG) factors also grows in importance.

Subjects like these aren't just important for compliance but performance in the public sphere. Companies are frequently told to make adequate disclosure in all their public filings.

Innovative R&D

R&D necessary for innovation is more important than ever for life sciences companies. Building on R&D for competitive advantage can include constructing diversified product pipelines, mapping out extensive exploration plans, sequencing trials, or compiling a list of investigational new drug (IND) applications.

The FDA approved 50 new drugs in 2021, either as new molecular entities (NMEs) under new drug applications (NDAs), or as new therapeutic biologics under

biologics license applications (BLAs). These novel drugs are notable for their potentially positive impact and unique contributions to patient care.

Innovative R&D continues to come to the forefront. While the benefit of new cures may potentially outweigh the cost, strict compliance checks are imperative. A single glitch could put a lot at risk.

These dynamics were again observed in the 2021–2022 SEC comment letters, with R&D being the largest area of scrutiny. As the majority of filings under review were Form S-1 prospectuses, there was an emphasis on objectively describing the R&D pipeline, process of clinical trials, and product purposes.

Create Clear Disclosures

Life sciences companies operate in a stringent regulatory environment, given the substantial impact their products can have on health and well-being.

Qualitative and quantitative information are equally important to disclosures in public filings. Firms must objectively describe what their operations are and where their current products or upcoming candidates stand in the market.

Statistics from financial statements or market data must reflect their claims accurately.

The need to use cautious language in describing business operations, product portfolios, and the operating environment was as important for life sciences companies in 2021–2022 as it was in last year's report.

The SEC again placed considerable emphasis on language in reviewing Form S-1 prospectuses. It required many applicants eliminate conclusory statements about product candidates that inappropriately signify their safety and efficacy, as that's determined by the FDA and comparable regulatory bodies.

Companies must be able to distinguish between descriptive and conclusive terms or phrases and be cautious when using them in a prospectus.

Apart from this, the SEC's focus on numerical disclosures pertaining to pro forma financial statements under Article 11 considerably increased this period. Companies filing on Form S-1 were asked to thoroughly update their statements, make sure all relevant events have been included within them, and describe all requisite calculations pertaining to gains or losses on shares.

Ramp Up ESG

ESG factors have become important in many industries including life sciences, and their importance towards earning consumer trust, community acceptance, and investor valuation shouldn't be overlooked.

This trend also showed up in comment letters. While SEC scrutiny on climate change reporting didn't directly impact young and middle-market life sciences companies this period, it did attract comments for the larger Form 10-K filers.

These companies were asked to identify and address the impact, direct and indirect, of existing climate change regulations on their businesses, as well as how this trend can alter their operational procedures and results of operations.

This included, for example, acknowledging that there may be an expectation that demand will grow for products that produce lower greenhouse gas emissions and how companies plan to integrate them into their offerings. It further included disclosing any material risks that climate change, for example weather changes or climate volatility, can pose on their operational ecosystem.

As per Fenwick & West's IPO market survey, life sciences executives and investors agree that the effect of ESG considerations will, at the very least, not decrease, while many expect it to become more critical throughout 2022.

Simplified, Meaningful Disclosure Framework

The SEC implemented several regulatory amendments over the past two years in efforts to modernize and improve disclosure requirements. The objective is to emphasize disclosure of all information material to investors yet avoid unnecessary or duplicative disclosure and simplify companies' compliance efforts.

Apart from the changes captured in the last report, the SEC has additions to the regulatory table. These are intended to keep regulations in line with the developing business environment.

Cybersecurity

On March 9, 2022, the **SEC proposed amendments** to its rules to enhance and standardize disclosures regarding cybersecurity risk management, strategy, governance, and incident reporting by public companies.

It also modified accounting standards to account for the rise of cryptocurrency and digital assets, requiring companies disclose all related risks in their financial statements.

Climate-Related Risks

On March 21, 2022, the SEC proposed rule changes that would require registrants to include information on **climate-related risks** that can affect their business, results of operations, or financial condition, as well as incorporate certain climate-related financial statement metrics in a note in their audited financial statements.

On May 25, 2022, the SEC proposed amendments to rules and reporting forms to promote consistent, comparable, and reliable information for investors concerning funds' and advisers' incorporation of ESG factors.

SPAC Disclosures

On March 30, 2022, following the 2021 SPAC bubble, the **SEC proposed new rules** and amendments to enhance disclosure and investor protection in IPOs by SPACs, and in business combination transactions involving SPACs and private operating companies.

The goal is to ensure investors receive the same treatment in terms of information symmetry and holistic disclosure as traditional IPOs.

Executive Compensation

On August 25, 2022, the SEC adopted amendments to its rules to require registrants to disclose information reflecting the relationship between executive compensation actually paid by a registrant and the registrant's financial performance. The rules implement a requirement mandated by the Dodd-Frank Act.

Registrants must begin to comply with the **new disclosure requirements** in proxy and information statements that are required to include Regulation S-K Item 402 Executive Compensation disclosure for fiscal years ending on or after December 16, 2022.

These various amendments and proposals are efforts to keep up with changing market conditions. The aim of these changes is to ensure consistent and complete information delivery throughout new developments and encourage stable growth.

It's critical to understand these evolving compliance requirements to prevent procedural delays in filing for an IPO or making recurrent public filings.

SEC COMMENT LETTER REPORT

RATIONALE

The objective of SEC comments is to preserve market confidence by helping companies prevent discrepancies and bring greater transparency to investors.

The rationale of this SEC comment letter report is to identify, understand, and analyze comments made by the SEC in the past, to derive insights and encourage proactive preparedness for SEC registrants.

This report specifically examines SEC comments related to Forms S-1, 10-K, 10-Q, and 20-F filings in 2021–2022, identifying possible patterns and changes in SEC staff focus in relation to the 2020–2021 study.

METHODOLOGY

To perform our analysis, we categorized all SEC comments issued to companies in select life sciences subindustries during the review period.

The following subindustries were covered in our analysis, identified by the SEC's electronic data gathering, analysis, and retrieval system (EDGAR) Standard Industrial Classification (SIC) code.

EDGAR SIC CODE	SUBINDUSTRY
2833	Medical chemicals and botanical products
2834	Pharmaceutical preparations
2835	In vitro and in vivo diagnostics substances
2836	Biological products (no diagnostic substances)
3826	Laboratory analytical instruments
3841	Surgical and medical instruments and apparatus
3842	Orthopedic, prosthetic, and surgical appliances and supplies
3843	Dental equipment and supplies
3844	X-ray apparatus and tubes and related irradiation apparatus
3845	Electromedical and electrotherapeutic apparatus
3851	Ophthalmic goods
8731	Commercial physical and biological research

Because middle-market companies were the focus of our study, we excluded from our research and assessment comments related to companies with market capitalization greater than $2 billion on the dates of analysis, which were August 4–5, 2022.

Our analysis included comments filed on the SEC EDGAR database during the period from May 1, 2021, to April 30, 2022, which we'll refer to as 2021–2022.

To achieve a fair and objective assessment of the data, we considered only the first instance of an SEC comment letter for an individual filing, given that, in subsequent instances, letters from the SEC often contained comments of similar nature to those found in the first iteration, or enhanced the previous comments if not appropriately addressed.

While the period of analysis under our current and previous reports, known as 2021–2022 and 2020–2021, respectively, was for 12 months, we nevertheless used a ratio-based methodology to generate comparable data across the years.

We considered cases when shifts in comment ratios in a subset of comments from 2020–2021 to 2021–2022 exceeded the mean variance in that subset to be significant variances over the last two years.

For example, out of the 1,424 comments directed toward Form S-1 filings in 2020–2021, 172 were related to entity background, amounting to a ratio of approximately 12.1%. The same ratio increased to roughly 14.9% in 2021–2022, an increase of approximately 2.8%. Because this was greater than the mean variance among other topics in Form S-1 filings over the stipulated period, we considered the variance in entity background-related comments toward Form S-1 filings to be significant.

Finally, some of the comments in this report were edited in the interest of clarity and brevity. Identifiable information, such as the names of companies, products, places, and dates, as well as dollar figures, were omitted in the SEC sample comments sections.

SECTION ONE

Overall Trends

An aggregate 1,625 comments were issued in response to Forms S-1, 10-K, 10-Q, and 20-F filings in 2021–2022, a further 8.6% increase to an already high comment count of 1,497 in 2020–2021.

Comments were largely spread across key comment categories; those related to R&D were most prominent with a 20.1% share. Like the previous study, the SEC continued its focus on ensuring complete disclosure when it comes to companies' clinical trials and studies, and requiring clarity and objectivity regarding developmental products and pipelines.

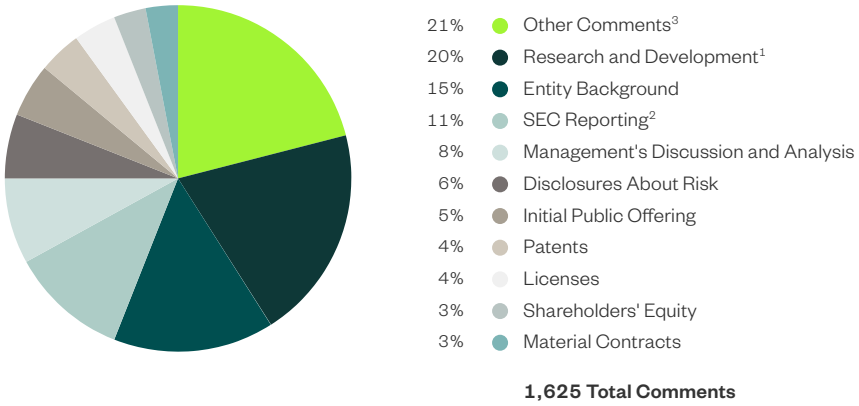
Entity background is the next major category this period, at a share of 14.6%. The SEC placed considerable focus on requiring registrants to thoroughly describe business operations in the beginning of the prospectus, including detailing the current offering mix, market dynamics, and regulatory scope.

SEC reporting—or process compliance—was next at 10.8%. Most comments, as in the 2020–2021 study, asked companies to make requisite and consistent disclosures throughout their prospectus, including filing all material information.

Comments requiring disclosure on management's discussion and analysis (MD&A), current and anticipated risks related to the business, as well as details on the actual offering and use of proceeds followed.

Information around underlying patents, licensing agreements, shareholders' equity, and material contracts constituted another significant block of SEC scrutiny, followed by various other comments targeting firm-specific controls and regulatory features.

FIGURE 1: Overview of SEC Comment Categories



[1] R&D comments relate to clinical trials and studies, FDA filings and communication, product pipeline, products and services, and other highly firm-specific information.

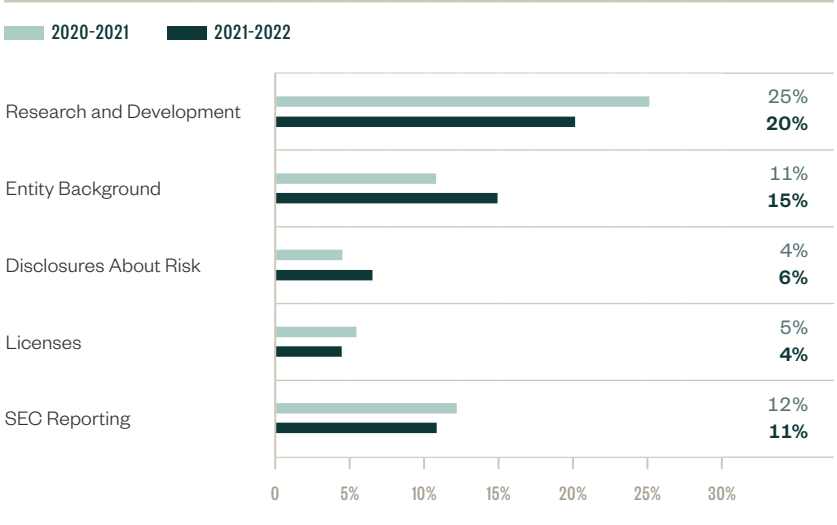
[2] Comments related to process compliance tend to be more administrative and formulaic, but because of the sheer volume of such comments, companies have an opportunity to significantly reduce filing delays by understanding the nature of scrutiny under this topic and taking the appropriate steps to comply.

[3] Other recurring comments include those related to emerging growth companies, controls and procedures, proxy disclosures, revenue recognition, and language-related matters.

SIGNIFICANT SHIFTS

Some topics saw a slight-to-significant shift in focus when compared to 2020–2021, with the positive or negative variance measured as a ratio to the total number of comments. This included categories such as R&D, entity background, risk-based disclosures, licensing agreements, and process compliance.

FIGURE 2: Significant Shifts in SEC Focus for Overall Filings
By Ratio of Comments



Comments related to entity background and risk-based disclosures increased in focus by 3.1% and 2.1% respectively. Comments directed toward R&D decreased by 4.9%, while those related to licensing agreements and process compliance slightly decreased by 1.8% and 1.4% respectively.

The mean variance of overall comments slightly decreased from 1.8% in 2020–2021 to 1.3% this period, given the moderate shift in total number of comments and categorization spread.

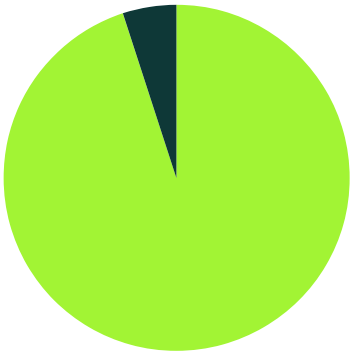
Except for certain categories such as R&D and entity background—which saw some fluctuation in focus—the nature and composition of comments over the last two periods remained fairly consistent.

COMPOSITION BY FILING TYPE

Similar to prior years, Form S-1 filings continued to lead in relation to SEC scrutiny. Of the 1,625 total comments analyzed in the study, roughly 92%—1,487 comments—were directed at Form S-1. This is a slight decrease from a share of 95% in 2020–2021.

The remaining 8% of comments were directed toward Forms 10-K, 10-Q, and 20-F filings.

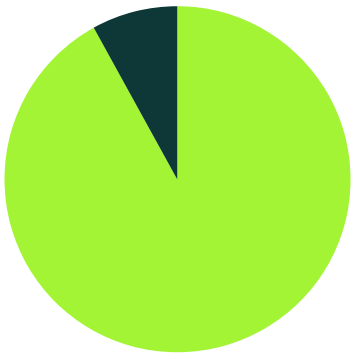
FIGURE 3: Percentage of Comments
By Filing Type



2020-2021

95% Form S-1 Filings
5% Forms 10-K, 10-Q, 20-F Filings

1,497 Total Comments



2021-2022

92% Form S-1 Filings
8% Forms 10-K, 10-Q, 20-F Filings

1,625 Total Comments

Similar to the 2020–2021 study, the nature of comment categorization varied among pre- and post-IPO companies. Form S-1 comments related to R&D, entity background, process compliance, and the actual offering remained dominant, while those related to risk-based disclosures came into greater focus this period.

The SEC required pre-IPO candidates to be comprehensive when it comes to making disclosures about their business operations, making sure they provide a

clear and transparent picture to investors about their organizational existence and background.

Applicants were largely asked to do the following:

- Expand on entity structure and background to highlight if operations are preclinical
- Give an unambiguous picture of products under development, providing an objective timeline across each phase
- Provide a holistic picture of the regulatory scope
- Map a clear plan for utilization of proceeds

In contrast, the nature of scrutiny was differently placed for post-IPO filers. MD&A remained the focus, like last period, with the SEC requiring many companies to be clear and consistent with disclosure of operational results year-over-year.

They were asked to, among other things, provide requisite calculations for certain financial metrics, outline the accounting guidance relied on throughout their statements, as well as explain the implication of macro volatility on results.

Comments for Forms 10-K, 10-Q, and 20-F filings remain focused on disclosure related to operational performance and recurrent procedural compliance. The operational backgrounds of these companies are already in the public domain; consequently, it's their annual disclosure on results and outlook that remain in prime focus.

NUMBER OF COMMENTS ISSUED

The number of SEC comments issued to companies rose consistently since the COVID-19 outbreak. The 2020–2021 study showed nearly twice as many comments as the 2019–2020 study.

While the rate slowed, the number of comments continues to increase.

This trend can be attributed to a few factors. The life sciences industry continues to operate under a hot activity stream, given that demand for health care solutions catapulted since the pandemic.

A lot of young companies are deriving solutions to meet a range of unmet needs including COVID-19, and going public to obtain the necessary funding. As the number of these Form S-1 registration statements increase, the scope for SEC review and comments also increases.

Also, the average Form S-1 inherently attracts more SEC comments than Forms 10-K, 10-Q, and 20-F. Applicants going public for the first time may attract more scrutiny given their limited experience in public disclosure requirements, as well as the greater depth of information they must convey to investors in the initial stage. These comments particularly spike even higher for reviews of draft registration statements (DRS).

As in 2020–2021, a substantial number of comment letters this period were in response to Form S-1 filings, and to the DRS. Consequently, the total number of SEC comments under the purview of this study continued to ramp up.

While the life sciences IPO market slowed since early 2022, the industry is still rapidly innovating and developing products. While the number of companies expanding and going public in any given year may ebb and flow, the trend of life sciences IPOs is expected to continue to remain steady in the coming years.

The goal for first-time filers should be to comprehensively understand filing and disclosure requirements before submission to get the process right the first time and reduce SEC questions and comments.

Trends in Form S-1 Filings

As expected, Form S-1 filings claimed more SEC attention than other filing types, making up 1,487 comments. That's 92% of the total 1,625 comments under review, marginally down from 2020–2021 when Form S-1 comments made up 95% of the mix.

FIGURE 4: SEC Comment Categories for Form S-1 Filings

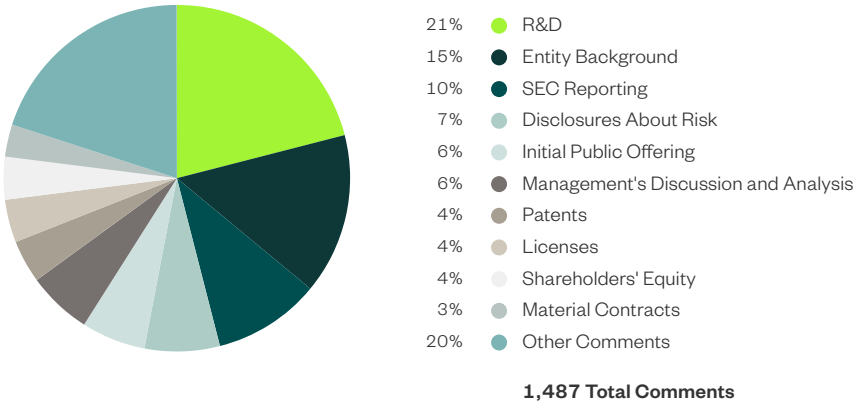
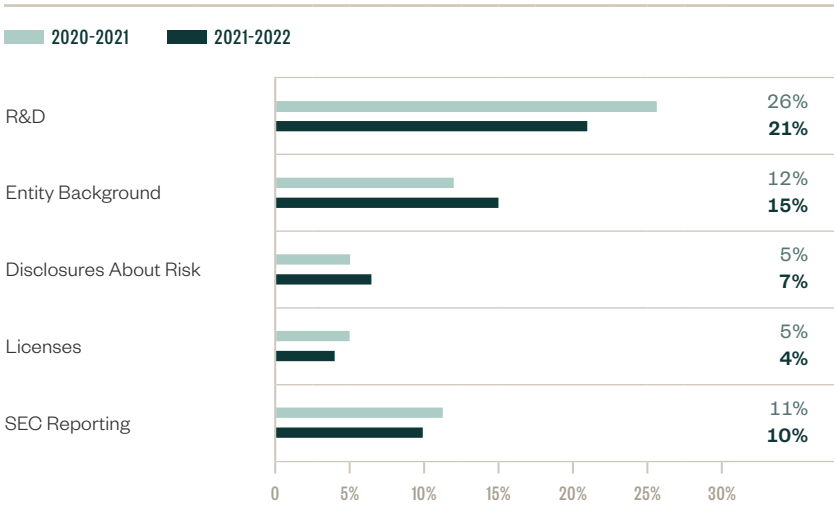


FIGURE 5: Significant Shifts in SEC Focus for Form S-1 Filings
By Ratio of Comments



In our comparative analysis, we noted categories that made slight to significant shifts relative to the 2020–2021 study. Comments related to entity background and risk-based disclosures gained greater prominence this period, increasing by 2.8% and 1.9% respectively.

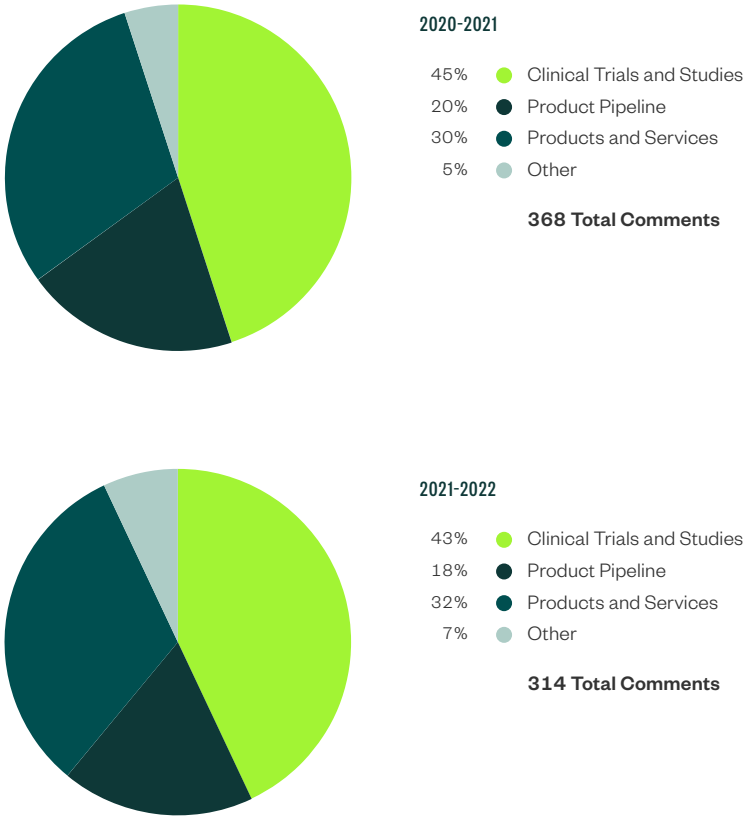
Focus on R&D dropped by 4.7% while focus on licensing agreements and process compliance decreased by 1.7% and 0.9% respectively.

The mean variance for Form S-1 comments decreased from 1.9% in 2020–2021 to 1.2% this period, highlighting lesser movement in the categorization spread. Certain salient topics continued to attract a large part of SEC scrutiny.

These key topics are examined in further detail in the coming sections.

R&D

FIGURE 6: Number of Comments for Form S-1
By R&D-Related Subcategory



R&D lies at the heart of the life sciences industry, leading to innovation and diverse product delivery year-over-year. It makes up the majority of the industry's value chain, from both a time and cost perspective, and stands at the cusp of competitive advantage. R&D is also the most prominent category for SEC review every period.

Item 101 of Regulation S-K specifically requires registrants to describe their general business development and plan of operations. This includes, among other elements, the following:

- An explanation of material product R&D to be performed during the period covered in the plan
- Any anticipated material changes in number of employees in the various departments, such as R&D, production, sales, or administration

While the emergence of COVID-19 brought drug and vaccine development to the forefront, it's not the only driver. Awareness around general health and well-being drastically increased, and people are eager to treat previously overlooked, lingering comorbidities and conditions. This pushed a host of life sciences companies big and small to broaden their R&D portfolios and tighten their product development timelines.

Speed is not the only factor, however. Designing quality solutions that are presumably safer and more patient-friendly than existing therapies in the market is a rising trend. Companies are also rolling out variants of existing therapies with these added benefits as a differentiating factor. Deciphering the validity of these statements and their actual market acceptance is another factor.

Given the criticality of these issues, R&D prompted the greatest number of Form S-1 comments this period, making up 21.1%. While this decreased from a share of 25.8% in 2020–2021, the importance of this category in relation to all others remained.

Within this category, comments directed toward clinical trials and studies stood out with a 43% share. Comments related to products in development and product pipelines followed, at shares of 32.5% and 17.8% respectively.

Other topics prompted a range of comments requiring greater disclosure on FDA filings and communications for developmental candidates as well as the costs undertaken to develop them.

CLINICAL TRIALS AND STUDIES

Similar to prior periods, clinical trials and studies stood as the most prominent subcategory in R&D in 2021–2022, making up 135 comments, or approximately 43%. This is a small drop from 2020–2021, when the topic made up 44.6% of total R&D comments.

Given the nature of this topic, the SEC placed most of its focus, like every year, on requiring companies to provide complete disclosure for all their clinical and pre-clinical studies.

This included details such as:

- Trial dates
- Sponsor
- Location
- Scope and size
- Duration
- Participant characteristics
- Dosage methodology
- Endpoints
- Final results

The disclosure of all serious adverse events (SAEs) observed in all clinical trials remains critical. To the extent that an SAE occurred, companies must clearly disclose the event and the number of affected patients.

Statistical significance is another important element. The SEC asked companies to disclose whether their referenced studies were designed to be powered for statistical significance. If so, they were asked to provide the p-values for

measurement, discuss how these values are used, and explain how statistical significance relates to the FDA standards of efficacy.

If not, they were asked to provide the implications of conducting testing and presenting efficacy results where the study wasn't powered for significance.

A pertinent area for scrutiny this time was the extent of involvement and control over collaborative trials and studies. The SEC required registrants to clearly describe their role in investigator-sponsored investigational new drug (IND) applications and to:

- Identify any agreements with the investigator
- Clarify any access to the data generated from the trials
- Describe the degree of control over trials

Because research is time- and cost-intensive, many companies work with other stakeholders in the industry, making a clear breakdown of roles and duties important.

Several comments this period were for companies working with consultants and clinical investigators in designing, monitoring, and analyzing clinical studies. The SEC requested such registrants discuss the roles of these stakeholders in all their clinical trials. This included describing and filing any material agreements entered for that purpose.

Companies were further asked to disclose, when collaborating with foreign third parties, whether results from other countries will be accepted in the United States without any repeat testing requirements.

Such disclosure of involvement and applicability isn't restricted to ongoing product trials but referenced studies as well. Registrants often make note of external studies or peer-reviewed publications to support the possible efficacy of their own candidates or platforms.

In this case it becomes imperative to highlight whether these companies themselves had any role in those studies, such as whether they funded or sponsored the studies or if their employees were involved in them.

Comments related to comparison and classification were as significant as in the past year's study. Companies must classify their trials to represent a true depiction of their progress, in phases for example, and avoid merging phases together unless they have formal approval to conduct multistage trials. This rule holds true for registrational trials or approvals under an accelerated pathway.

When comparing trial results where comparison isn't based on head-to-head studies, companies must concretely explain their reasoning and whether these comparisons can also be relied on to obtain other approvals.

Any graphic representation of the results must be clearly linked to the data with proper explanations.

In summary, all disclosures pertaining to clinical trials and studies must establish objectivity and causal linkages. Registrants must present a detailed methodology and observational mind map of their research to investors, where all claims are directly corroborated with concrete trial data.

Sample Comments

> *We note your statement on [page reference] that in the [study name] Phase 1 study, there were no deaths, serious adverse events (SAEs), or any adverse events leading to withdrawal from the study. Throughout this section, ensure that you disclose all SAEs and the number of patients who experienced them for all SAEs that were determined to be treatment related or that the investigator could not determine were not treatment related.*

Please revise the discussion of your parent company's research activities to clarify to what degree you control the progress of these studies, whether the products will be commercialized and the terms of any potential licensing agreement.

Please revise to include more detailed descriptions of each pre-clinical study conducted, including who conducted the study, the type and number of tests conducted, how the tests were conducted, the number of animal models or subjects used, the number of tests conducted, the range of results or effects observed in these tests, and how such results were measured. Expand your descriptions of any resulting data to include whether or not statistical analysis was performed, and if so, revise to indicate whether the results from each test were statistically significant and provide the relevant p and n values.

We note several comparisons to certain approved therapies in the Summary and in the Business section. If you have not conducted head-to-head trials, please revise your disclosure to clearly state this fact and disclose why you believe these comparisons are appropriate. If you provide disclosure regarding results from other trials, expand your disclosure to provide the other information regarding these trials that would help an investor make a meaningful comparison and understand the supporting trials and any limitations and qualifications associated with such trials (e.g., number of patients and whether any patients dropped out of the trial or were otherwise excluded and the reasons, patient population, dosage, how the baseline was measured in each study, the phase of the trial, serious adverse events, etc.).

We refer to your disclosure on [page reference] and elsewhere in the prospectus to nine clinical studies and over 100 peer-reviewed publications demonstrating the efficacy, safety and durability of your [product name] therapy. Please revise your disclosure in this section and in greater detail elsewhere to disclose, if true, whether you funded or sponsored the clinical studies and if your employees were involved in both the studies and publications.

Please expand your disclosure here to discuss the role of consultants and clinical investigators in your studies and trials. To the extent that you have material agreements with any consultant or clinical investigator on which you depend, please disclose the material terms of these agreements and file them as exhibits pursuant to Item 601(b)(10)(B)(ii) of Regulation S-K or explain the basis for your determination that filing them is not required.

DEVELOPMENTAL PRODUCT PIPELINE

Drug development is an intricate procedure with a series of chronological steps. Tasks like the initial scoping for a solution, running trials, and completing commercialization post-approvals all take time and money to get products from drawing boards onto shelves. It's critical that life sciences companies thoroughly communicate the timeline of each developmental product.

In a prospectus, this disclosure is typically made in a product pipeline table that demonstrates—both graphically and textually—which stage of development each candidate is in.

Comments in this area made up 17.8% of total R&D comments this period, which is a slight drop in share from 19.6% in 2020–2021. The significance of this topic, however, is the same as other years, with the SEC scrutinizing pipeline tables.

Comments were similar to prior periods. Registrants were asked to review the presentation of their tables for a fair and transparent diagrammatic view of the portfolio horizon. This included the following key pointers:

- Include separate columns for each material stage that needs to be completed before marketing. For example, separate columns for each clinical development phase like Phase 1, Phase 2, and Phase 3.

- Condense preclinical phases to no more than two columns. For example, phases like lead optimization and discovery might come under the same segment in the pipeline table. A textual discussion of the program is a more appropriate place to make distinctions regarding different segments within a particular phase.
- Place appropriate-length arrows next to each program to show its progress and make sure not to encroach on phases not yet started. The arrows should give a fair representation of the current relational pipeline and not overstate the picture.
- Make sure the pipeline table is limited to only those products that are material to the company. Programs that are too early in the discovery phase should be removed or otherwise supported with adequate reasoning that warrants their inclusion.
- Keep the table consistent with narrative disclosure about those programs made throughout the prospectus, as well as any claims made about them on publicly available sources.
- Touch on any collaborations with other third parties or licensing agreements that the products under development are dependent on.

They key takeaway here is the need for concise and precise disclosure with diagrammatic representations giving a fair picture of timelines. Time is a significant factor in the life sciences industry, where long R&D gestation periods are affected by market uncertainty.

Sample Comments

> *Please provide additional disclosure about why the first three arrows in this pipeline table are different lengths when it appears that all of these Phase 2 clinical trials are still enrolling patients. While we understand that your website is not incorporated by reference into the prospectus, we note that the pipeline table on your website breaks down these three Phase 2 trials into Phases 2a and 2b. Please consider whether similar disclosure, either in the pipeline table itself or a separate narrative description, would be appropriate in this prospectus.*

> *Please revise your pipeline table to condense the preclinical phases to no more than two columns and to separately depict clinical phases 1, 2 and 3.*

> *With respect to your table on [page reference] showing your expected timeline for your product candidates, it appears to be premature and speculative to provide the estimated time to market for your product candidates given that it appears that you have yet to complete material steps in order to commercialize your product candidates. Please revise this table to provide the status of FDA approval of your various product candidates, including clinical trials or studies you must complete, when you began clinical trials or studies and when you expect to complete them and whether you have submitted or when you intend to submit an application for approval to the FDA.*

> *We note that you have nine programs in the discovery and the IND-enabling stage. Please explain to us why each of those programs is sufficiently material to your business to warrant inclusion in your pipeline table or revise your table as appropriate.*

PRODUCT-SPECIFIC INFORMATION

While representing the product portfolio in the pipeline table covers one aspect of a prospectus, supplementing this with holistic disclosure on each individual candidate under development is another aspect altogether.

There are a host of steps involved—from the time a new drug or therapy is conceived to its final commercialization in the market—and it's vital registrants clearly disclose each of these core steps in the prospectus.

SEC scrutiny related to product-specific information under development consequently remains strong every year. Comments in this topic made up 32.5% of total R&D comments in 2021–2022, further increasing from a share of 31.3% in 2020–2021.

Given the nature of this topic, the type of comments are company-specific year-over-year and there isn't really a systematic formula that can predict what the SEC will ask. However, there are certain key elements that come up repeatedly.

Companies must provide complete information as to why they targeted certain indications, what they aim to develop under each program, how their product candidates are progressing, what makes them unique, how they will eventually reach the market, and how they will be governed under the current regulatory scope.

Many such key elements that came up in this period's comment letters are summarized below:

Objective(s) of development	• What is the specific target indication? • How is this approach novel compared to existing therapies? • Are the drugs or components proprietary? • Do competitors use similar technology or approaches? • Is development largely preclinical?
Nature of product-specific trials	• Is there a niche type of patient population being sought? • What is the duration of patient treatment? • Are all comparisons based on head-to-head trials?
Intellectual property	• Is there any uncertainty whether claims in pending patent applications will be considered patentable? • Is there any reliance on intellectual property licensed from a third party? Possible implications as a result?
Statement of regulatory approval	• Are INDs submitted? If not, any rough idea of timelines? • Is there concrete evidence that the FDA has approved or is likely to approve certain candidates? • Are there other regulatory requirements the product candidate falls into? Is it operating in a highly regulated and stringent field?
Plans for development and commercialization	• Any plans for obtaining coverage and reimbursement? • Are there specific marketing and distribution plans in place? Will that change the regulatory scope for the candidates?

Language is an important component. Registrants must be cautious in making statements that incorrectly imply a faster regulatory route or guaranteed success rate for a product candidate, given that clinical development is inherently a long and uncertain process for any company.

Use of phrases such as "we aim to rapidly advance product XYZ into clinical development" should be avoided as they incorrectly imply successful commercialization of candidates in an accelerated manner. These statements are speculative and outside any company's control.

There's no procedural secret recipe for excelling in product-related disclosures. Making objective, comprehensive, and holistic disclosures can mitigate the scrutinizing comments.

Sample Comments

> *We note your disclosure that you intend to "[r]apidly advance through clinical trials and eventually obtain regulatory approval for [candidate name] for the treatment of [disease name]." Please revise this disclosure to remove any implication that you will be successful in commercializing your product candidates in an accelerated manner, as such statements are speculative and outside of the company's control given the extensive regulatory process and approvals required. Ensure that similar language throughout the prospectus is also removed.*

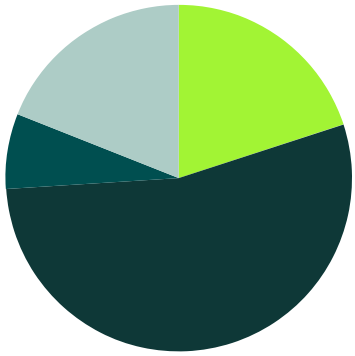
> *We note your disclosure that results from your [trial name] may provide support for the accelerated approval of [drug name] for patients with advanced solid tumors harboring an [disease type], subject to discussions with the FDA. Please also include balancing disclosure that you will still be required to conduct post confirmatory trials to confirm the anticipated clinical benefit of your product candidate and that the accelerated approval process may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that it will receive marketing approval.*

> *Please revise to discuss the status of development of each of the research initiatives/ new product candidates identified, including a discussion of your product candidates for [disease name].*

> *For each of the 11 indications identified on [page reference], please disclose the phase of FDA approval process for each product, and disclose a brief explanation of the FDA approval process, including a discussion of the general timeline and the fact that approval may never be obtained.*

ENTITY-RELATED INFORMATION

FIGURE 7: Number of Comments for Form S-1
By Entity-Related Subcategory



2020-2021

20%	Market
54%	Products and Services
7%	Regulations
19%	Other

172 Total Comments

2021-2022

15%	Market
56%	Products and Services
10%	Regulations
19%	Other

222 Total Comments

Context matters. Making comprehensive disclosures on the business background and operations is necessary for every company, especially those going public for the first time.

Investors need to understand the contextual picture behind procedural disclosures and have a thorough understanding of what each company does, its business model, and where it is in the industry matrix.

The scope of disclosure for entity background largely revolves around the following key parameters year-over-year:

- Entity's main mission and objective
- Business model and revenue streams
- Positioning in the external environment including competitive landscape, market potential, and size
- Overview of the existing products and services portfolio including rough segmentation of revenue breakdown
- Collaborative arrangements including ones that detail key intellectual property rights
- Regulatory scope
- Organizational structure

- Background of related persons, promoters, and certain control persons, pursuant to Item 404 of Regulation S-K

There were an aggregate 222 comments pertaining to entity-related information this period, making up 14.9% of total Form S-1 comments. This is up from a share of 12.1% in 2020–2021.

Similar to the previous study, comments related to current products and services and the external environment had most of the SEC's focus, followed by those related to the regulatory scope.

EXTERNAL ENVIRONMENT

Markets constantly evolve, and no business is immune to change. Issues such as COVID-19 and ongoing global political tensions created volatility, making it critical to monitor developments.

However, markets are not just about change. Defining an addressable market is important as it positions the company and its products in the industry ecosystem. Registrants need to be able to unambiguously communicate quantitively and qualitatively the exact demand dynamics for their products.

While the absolute number of market-related comments stayed the same at 34, the relational share in total entity-related comments dropped from 19.8% in 2020–2021 to 15.3% in 2021–2022. Despite this, the topic was one of the top three subcategories in entity background disclosures.

The SEC continued to emphasize accuracy and reliability when it comes to making estimates or conducting studies for addressable markets. Registrants were asked to validate claims about market size and provide a concrete basis for calculations and statistics, citing any third-party sources, assumptions, or limitations as necessary.

Breaking down broader markets into segments remained an area of significant focus. The SEC asked registrants to break down large numbers and provide the actual proportion of markets that were directly addressable by their products or product candidates.

Knowledge of competition was a key area this period. The SEC required many registrants to identify and qualify their principal competition and whether any competitors were developing similar lines of treatment.

An objective, calculated focus on market dynamics is a key way to avoid SEC comments.

Sample Comments

> *Please expand your disclosure to include the key assumptions underlying the prediction that the US legal cannabis market will more than double by 2025.*

> *Please balance your disclosure in this section by describing the categories into which your products and services fall and your market position across relevant product categories, or the nutraceutical industry in general, based on the data and information you rely upon.*

> *Please disclose whether, to your knowledge, any of your competitors are developing [disease] treatments for the same indications for which you are developing your treatments.*

PRODUCTS AND SERVICES

Background on a company's existing products and services portfolio is fundamental to a prospectus.

Comments regarding products and services again constituted most entity-background comments, with the share further increasing from 54.7% in 2020–2021 to 56.3% this period.

The Overview section of the prospectus is where registrants provide a clear picture of their entity-wide operations to date, including their current offerings and revenue streams, if any, as well as how they're expanding the line with new candidates. This includes describing whether they designed any in-house, proprietary technology to facilitate product development and how that helps them differentiate from competitors.

Similar to the Products & Services topic in R&D, SEC scrutiny here remains largely company-specific and there isn't a sure-fire framework companies can systematically follow to fulfill the requirement. However, several factors show up in comments and paying attention to these elements can help clear up doubts.

Some key areas in which the SEC required registrants to make more expansive disclosure in this period's Form S-1 filings are as follows.

Product and service characteristics	• Target indications and markets being addressed • Differentiating factors • Receipt of key industry certifications • Platform features • Operating history, such as the time it took to develop, get approval or clearance, and start marketing • Geographical footprint • Time in market
Ownership of rights	• Self-owned or licensed from third parties
Production and sales	• Manufacturing facilities, time, cost, and capacity • Inventory shelf life • Distribution channels and strategy • Customer interaction
Dependency on collaborative arrangements	• Disclosure on single-source suppliers or customers • Any partnership with other stakeholders such as physicians, surgeons, or service providers who will be actively involved in rendering operations
Revenue breakdown	• Share between different products and services
Expansion plans	• Scaling up current operations • Expanding geographical reach

Within these topics, disclosure on sources and availability of raw material was highly emphasized, with the SEC requiring many registrants to include the names of their principal suppliers, identify any agreements with them, and file such agreements as exhibits to the statement, pursuant to Item 101(h)(4)(v) and Item 601(b)(10) of Regulation S-K.

Language remained a critical feature, as in the last period. Avoid phrases like "We are a world-class company" or "We provide premier and next generation products" unless the company has concrete supporting evidence. Just as in R&D, any statement made about past, present, or future operations must be objective.

If a registrant's operations are preclinical or hasn't yet generated revenue, it should be clearly mentioned in the Summary section.

A balanced, precise, and concise disclosure is key. Registrants should provide a balanced and factual representation of their business, discussing both the competitive advantage of their business models, as well as all underlying challenges.

However, they must also refrain from going too deep, as a more detailed discussion would follow in the Business section. For example, a discussion of key investors in the company is more suited in the Principal Stockholder section than in the prospectus summary, as this isn't a subject investors need full knowledge of when making investment decisions.

Sample Comments

> *Please expand your disclosure to address the sources and availability of raw materials as well as to include the names of your principal suppliers. Furthermore, to the extent that you have agreements in place with these named entities or other suppliers, please describe the material terms of these agreements in your disclosure and file these agreements as exhibits to the registration statement, or, in the alternative, please tell us why you believe that you are not required to file the agreements. Refer to Item 101(h)(4)(v) and Item 601(b)(10) of Regulation S-K.*

> *Please expand your disclosure to describe for each operating segment the products you offer, the performance of those products or product categories and the channels through which you sell and distribute your products.*

> *Expand your summary to explain how you acquired the rights to your products. Did you develop them in house or acquire them from other parties? If acquired, please describe your acquisition or licensing agreements and all material terms. Please either file the agreements or provide us with an analysis supporting your determination that the agreements are not required to be filed.*

> *Please revise this opening paragraph to explain that your operations are preclinical.*

> *Your Summary should provide a balanced and factual presentation of your business. Please revise to discuss your competitive position and the challenges you face in implementing your business strategy.*

REGULATORY SCOPE

Comments pertaining to the regulatory scope made up 9.9% of total entity-related disclosures in 2021–2022, up from a share of 7% in the previous report.

Given the stringent regulatory nature of the life sciences industry, coupled with the fact that many companies now use controlled substances to develop breakthrough therapies for multiple markets, the importance of regulatory disclosures can't be emphasized enough.

The SEC continued to require registrants be clear in discussing relevant government regulations that affect each area of their business operations. It also requested they include those rules that impact only specific products or product candidates, describing whether this can place any restriction on potential sales.

In cases where the commercialization of a drug was dependent on acquiring one or several approvals or renewals of certain contracts, registrants were told to

clearly list all obligations they had to fulfill. Registrants were told to highlight in the prospectus summary that there was no guarantee they would be able to meet those obligations and market their drugs.

With the emphasis placed on environmental, social and governance (ESG) reporting, companies were also asked to discuss the costs and effects of compliance with environmental laws at the federal, state, and local level that could materially impact their business.

SEC scrutiny on registrants' regulatory landscape is likely to grow. As companies continue to expand their geographical outreach, from production hubs to distribution facilities to offshore R&D centers, the purview of applicable regulations is widening.

Foreign parents are also extending their footprint through subsidiary establishment, bringing a complex web of control and duties. Maintaining comprehensive disclosure of all compliance avenues will remain important.

Sample Comments

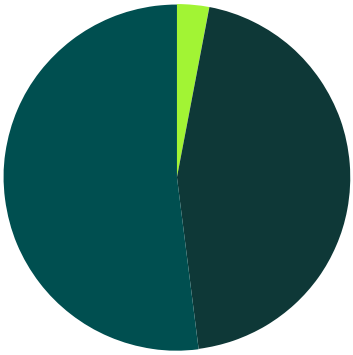
> *We note your disclosure in the Business section on [page reference] that you may not commence cannabis growing operation until both the [state reference] and the federal government or its authorized agencies, in particular the DEA, have signed off and fully authorized that you are in full compliance of all applicable rules. Please revise your disclosure in the Prospectus Summary to include a similar statement.*

> *Please revise your disclosure to discuss the effect of all material existing or probable governmental regulations on your business, including, for example, the potential for regulation by the FDA. Please also discuss the costs and effects of compliance with environmental laws at the federal, state, and local level that may materially impact your business. Refer to Items 101(h)(4)(ix) and (xi) of Regulation S-K.*

> *We note your disclosure that you intend to conduct trials and pursue marketing authorizations with [candidate name] in additional geographies outside of the United States and Europe, with an initial focus in Japan. Please discuss regulatory approval requirements in Europe and Japan under an appropriate heading in the Business section.*

RISK DISCLOSURES

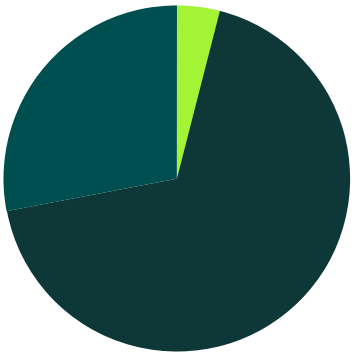
FIGURE 8: Number of Comments for Form S-1
By Risk Disclosures Subcategory



2020-2021

3%	Going Concern
45%	Risk Factors
52%	Updated Disclosures

66 Total Comments



2021-2022

4%	Going Concern
68%	Risk Factors
28%	Updated Disclosures

97 Total Comments

Risk is an inherent part of the business ecosystem with each industry facing its own set of challenges and uncertainty. In the fast-paced life sciences sector, issues such as the need for constant innovation, technological advancement, product approvals, obsolescence, discovery, intellectual property, and regulation stand at the forefront. Players grapple with achieving breakthrough solutions and getting products on the market on time and ahead of the competition.

These issues can further be hindered by volatility, both externally and internally. A prime example of an external shock would be COVID-19, which led to a series of setbacks ranging from lockdowns to mobility hits and supply chain disruptions. On the other hand, internal volatility can also emerge from a company's own operational dynamics, such as its management structure, manufacturing capabilities, compliance metrics, and more.

Being able to anticipate, identify, measure, mitigate, and disclose these issues is of high priority, especially for firms going public for the first time.

Item 105 of Regulation S-K stipulates filers provide a discussion of the material factors that make an investment speculative or risky, and label it Risk Factors. Such discussion must be a key section in the prospectus. Each relevant risk factor should be set apart with a subheading and a detailed explanation of how such a risk affects the registrant and the securities being offered.

SEC scrutiny related to risk-based disclosures is consistently rigorous. This period, 97 comments made up 6.5% of total Form S-1 comments, up from a share of 4.6% in 2020–2021. The majority of comments centered on companies' risk-factor discussions, followed by those requiring updated disclosures and elaboration on going concern issues.

Registrants were asked to describe specific risks arising across all areas of operation. These risks can stem from the external environment or within the firm.

Examples include risks driven by:

- **Product development.** Performance in clinical trials, safety concerns, data validity, and other areas.
- **Regulatory backdrop.** Clinical holds, approval delays, added scrutiny, or possible exemptions.
- **Competition.** Possible potential substitutes, price wars.
- **Debt and valuation.** Chances of default, financial pressure, and possible asset cuts.
- **Intellectual property rights.** Ownership variability, licensing dependency and restrictions, and march-in rights.
- **Management control.** Dilutive effects, concentration of ownership, voting power, and structural volatility due to conflicting interests and roles.
- **Process orientation.** Internal and digital controls.
- **Material dependency.** On suppliers, customers, distributors, or other stakeholders.
- **Legal disruptions.** Due to geographical spread and control of operations.
- **Going concern.** Recurring losses or dearth of capital resources affecting future operations.

Risks associated with exclusive forum provisions were in significant focus. Many comments required registrants to disclose there is a risk that their exclusive forum provision may result in increased costs for investors to bring a claim.

Emerging growth companies that used the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the 2012 Jumpstart Our Business Startups (JOBS) Act were asked to explain the risks of this delay. This included explaining that they won't have financial statements directly comparable to companies that comply with public company effective dates.

Registrants who had substantial doubt about their ability to continue as a going concern, including an Emphasis of Matter paragraph relating to going concern in the auditors' opinion, were asked to give more detailed disclosures about the risk to investors. Precise information was required on exactly how long they can sustain operations and what contingencies exist for acquiring more funds.

Apart from requiring clarity in the above disclosures, the SEC continued to emphasize compliance with the amended Item 105. Registrants were encouraged to discuss the specific significant risks—as opposed to generic risks—affecting their business and keep the disclosure precise and concise.

Any discussion of generic risks was asked to be moved to the end of the section, under the general risk factors label.

Sample Comments

> *From the risk factors on [page reference] and disclosure elsewhere, it appears you are not obligated or tasked with the duty to defend your intellectual property, have control over your source of products or the quantity you must purchase, or have the ability to determine the future products you will seek to commercialize. Add a risk factor addressing the risks associated with the lack of control your management and board will have over your company and its direction given the current structure, the degree*

of control related entities have over your business currently through licensing and intellectual property agreements, in addition to their significant share ownership.

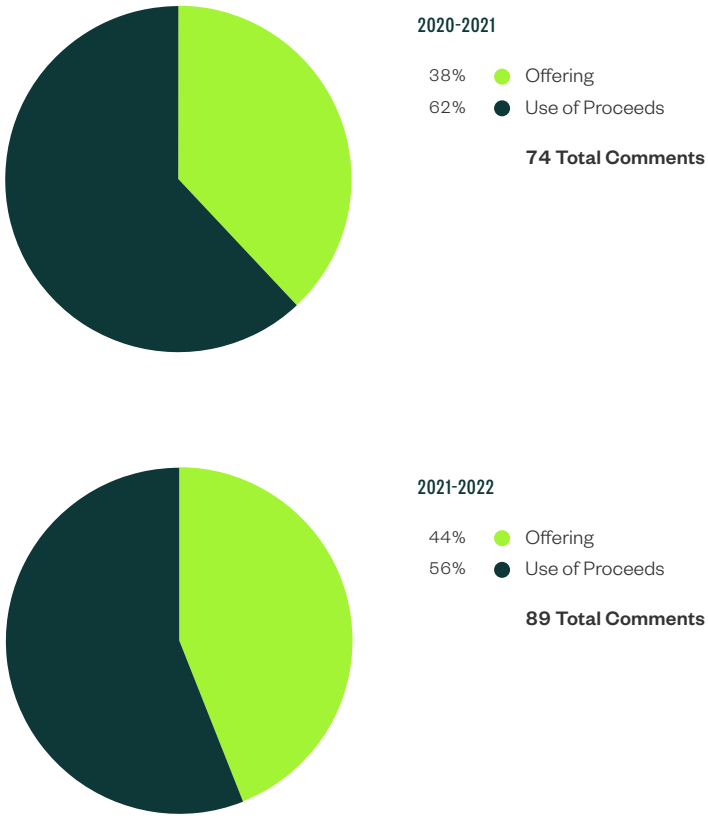
Please revise the discussion to disclose that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder and that there is also a risk that your forum selection provisions may result in increased costs for investors to bring a claim.

Your risk factor summary currently exceeds two pages. Please revise your risk factor summary to be no more than two pages and to discuss the principal factors that make an investment in you or in the offering speculative or risky, rather than listing each heading that appears in the Risk Factors section. For guidance, please refer to Item 105(b) of Regulation S-K.

Please revise to comply with Regulation S-K Item 105 by relocating risks that could generically apply to any registrant or offering to the end of the section under the caption "General Risk Factors."

IPO-RELATED DISCLOSURES

FIGURE 9: Number of Comments for Form S-1
By Initial Public Offering-Related Subcategory



Focus on IPO-related disclosures constituted roughly 6% of total Form S-1 comments this period, registering a slight increase from a share of 5.2% in 2020–2021.

These comments, as in the past, are procedural in nature. The SEC either required registrants to make specific disclosures related to the actual offering or clarify the use of proceeds.

These requirements mainly stem from Items 501 and 504 of Regulation S-K as well as compliance with rules and regulations under the Securities Act.

The goal is to help investors gain clarity on all offering terms and conditions and understand how registrants wish to utilize the proceeds.

This includes a clear-cut disclosure of key pointers such as:

- Offering type and price
- Description of securities
- Structure
- Underlying conditions
- Overall eligibility
- Use of proceeds

First-time IPO filers who are new to the public filing process itself have a greater chance of making incomplete disclosures and attracting SEC comments. It's possible to understand the pattern of comments that repeat each year and avoid those issues.

OFFERING

Comments related to the offering transaction constituted over 43.8% of total Form S-1-related comments in 2021–2022, up from a 37.8% share in the previous report, of which the majority pertained to IPOs.

As with previous periods, registrants were asked to expand their disclosure around the following areas:

- Description of securities on offer, including determination of price and number of securities to be registered, as well as termination date
- Existent market for such securities or clarification that no public market exists currently; this includes detailing which market or markets the registrant intends to list on
- Classification of the offering, basis current shareholding, and all prevailing circumstances
- Plan of distribution describing each function to be performed by financial advisors in connection with the offering
- Contingency provisions, such as whether the offering is contingent on securing listing approval in a market
- Underwriter compensation including the type and number of securities issued and their exercise price
- Registration of the offering under the Exchange Act and consequent implications
- Any agreements with financial advisors in relation to the registration of shares
- Nature of private investment in public equity (PIPE) arrangements, including details on the exercise price and any conditions imposed for investor participation
- Any amendments filed for the registration of resale of shares.
- Cross reference on the type of offering selected on the cover page with the rest of the prospectus

The SEC required registrants with no existent public market for common stock to disclose a fixed price at which their shares will be sold until the time they're on a national securities exchange or quoted on the OTC Bulletin Board, OTCQX, or OTCQB.

Sample Comments

> *We note several statements here and elsewhere throughout the registration statement that there "are no underwriters" or that the Advisor is "not acting as an underwriter." Please note that whether the financial advisors would be considered statutory underwriters requires an analysis of the facts and circumstances; therefore, please revise all of these references that imply the absence of underwriters, or that your financial advisors are not considered underwriters, to clarify instead that the direct listing does not involve a firm commitment underwriting. Please also ensure that your revised Plan of Distribution describes each function to be performed by your financial advisors in connection with the offering.*

> *We refer to your cover page disclosure indicating that no public market currently exists for your Common Stock and that you intend to have your Common Stock quoted on the OTCQB at some point in the future. Accordingly, please revise the cover page to disclose the fixed price at which the Selling Securityholders will offer and sell the shares until such time, if ever, that your Common Stock is quoted on the OTCQB or another existing market, and thereafter at prevailing market prices or privately negotiated prices. For guidance, refer to Item 501(b)(3) of Regulation S-K.*

> *Based on your disclosure, it appears that the reduction in the exercise price of the PIPE Common Warrants held by the institutional accredited investor from the Private Placement is contingent upon such investor's participation in your public offering. Please provide us with your analysis as to whether this arrangement is a privately negotiated arrangement with the investor in the Private Placement, and, if so, whether that impacts your eligibility to offer registered shares to such investor as part of the public offering.*

USE OF PROCEEDS

A clear plan for the allocation of funds is a pivotal part of every prospectus. It helps investors understand how registrants intend to use the funds raised to further their business objectives.

At the same time, having a detailed plan of action prevents companies from running into a disarray of funds, reducing the chance of waste or idle cash.

Consequently, the SEC's scrutiny of the use of proceeds, pursuant to Item 504 of Regulation S-K, maintains significant traction year-over-year. Comments pertaining to these disclosures made up over 56.2% of total IPO-related comments in 2021–2022, registering a slight dip from a share of 62.2% in the previous report. This topic again prompted most of the comments in Form S-1s notably for IPOs.

Similar to prior years, the SEC required registrants to clearly outline how they'd use the proceeds raised from the offering to meet their specified purposes, quantifying the breakdown for each. They were also required to identify any other material funding needed, stating the related sources and amounts.

The nature of disclosure varies by purpose. For example, if the proceeds are to be used for product development, registrants should estimate, for each product or program, how far in the clinical development process the allocated proceeds of the offering will enable them to reach.

If the proceeds are to be used to pay off debt, registrants should disclose the interest rate and maturity dates of all indebtedness, and describe the use of the proceeds of indebtedness incurred within the last year—in reference to Instruction 4 to Item 504 of Regulation S-K.

Registrants must make a specific and meaningful disclosure to describe the same—whether using funds to fast-track trials, obtain regulatory clearances,

pay transactional fees, discharge other capital expenditures, or forward the commercialization strategy.

The SEC required registrants with no specific action plan for a significant portion of proceeds to include a statement to this effect, discuss the principal reasons for the offering, and add a requisite risk factor disclosure.

Sample Comments

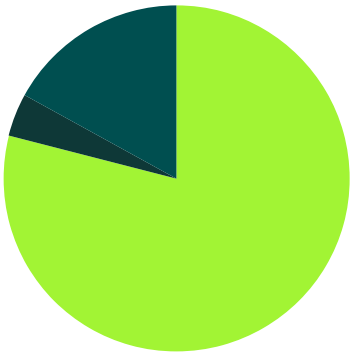
> *We note that you intend to use a portion of the net proceeds of this offering to pay off all debt that you owe to various note holders and term loan holders. Please expand to disclose the amount outstanding under those agreements as of the latest practicable date and the interest rate and maturity dates of all such indebtedness. Additionally, if any of the indebtedness was incurred within the last year, describe the use of the proceeds of such indebtedness. Refer to Instruction 4 to Item 504 of Regulation S-K for guidance.*

> *Please revise your disclosure that you expect to use net proceeds from this offering to fund further development of [candidate name], including the global Phase 2b/3 clinical trial, to provide an estimate of how far in the clinical development process for [candidate name] the allocated proceeds of the offering will enable you to reach. For example, if you will not complete the Phase 2b or Phase 3 portion of the trial, please revise to so state. If any material amounts of other funds are necessary to complete your clinical trials for this candidate, please revise your disclosure to state the amounts and the sources of such other funds. Refer to Instruction 3 of Item 504 of Regulation S-K.*

> *We note your revised disclosure in response to prior comment 2, including that you intend to use certain of the proceeds for working capital and miscellaneous corporate purposes and that you intend to use a portion of the proceeds for acquisitions, but you do not have any current agreements, commitments, or understandings for any specific acquisition. To the extent that you do not have a current specific plan for a significant portion of the proceeds, please include a statement to this effect, discuss the principal reasons for the offering and add risk factor disclosure. Refer to Item 504 of Regulation S-K.*

MANAGEMENT'S DISCUSSION AND ANALYSIS

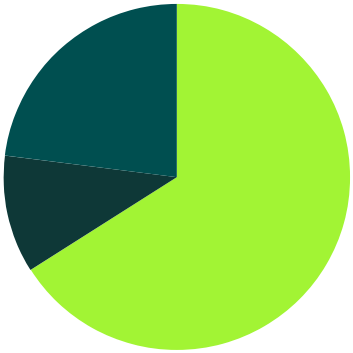
FIGURE 10: Number of Comments for Form S-1
By Management's Discussion and Analysis Subcategory



2020-2021

79%	Critical Accounting Policies
4%	Liquidity and Capital Resources
17%	Results From Operations

96 Total Comments



2021-2022

66%	Critical Accounting Policies
11%	Liquidity and Capital Resources
23%	Results From Operations

88 Total Comments

The MD&A section is an important part of public filings, and is required by Item 303 of Regulation S-K. Companies must discuss their financial condition and changes to such, in relation to the following key parameters:

- Liquidity and capital resources
- Results of operations
- Critical accounting estimates

Companies may also supplement this with disclosure of other information or parameters they believe material to the understanding of their financial condition and operational results. The key is to present a complete contextual picture behind financial statements, narrating the story behind those key operational numbers and signaling how they can change over time.

Item 303 also underwent significant changes under the SEC's modernization drive to become more company- and investor-friendly.

Among the changes, the mandatory disclosure of a contractual obligations table was removed while a principles-based instruction for off-balance sheet arrangements replaced the prescriptive disclosure requirements. The amendments went into effect February 10, 2021.

However, the goal is not to eliminate information. The necessity of basic parameters ensures companies present a transparent picture to investors about their ongoing operations, as well as discussing what lies ahead.

This overarching objective is to simplify disclosure requirements that eliminate repetitive or unnecessary disclosures, as well as open the canvas to companies and let them decide what information is specifically material to them and their investors and how best to disclose it.

Comments related to MD&A made up 5.9% of total Form S-1 comments in 2021–2022—a slight decline from a 6.7% share in 2020–2021. This topic remained a key comment category every year.

Similar to the last study, comments pertaining to critical accounting policies and estimates continued to make up the majority of MD&A comments, while those on operational results and liquidity and capital resources took a smaller share.

CRITICAL ACCOUNTING POLICIES

Comments directed toward critical accounting policies and estimates got the most SEC attention in MD&A year-over-year. This period a total of 58 comments made up 65.9% of the MD&A mix. While this is a decline from a share of 79.2% in 2020–2021, the importance of this topic in relation to all others remained intact.

Accounting policies play a crucial role in financial statements, but also the way businesses manage their operations. The methodologies behind how companies conduct inventory costing, value their shares, or account for complex agreements play a vital role in how their operational results and projects pan out.

Registrants are required to clearly disclose all material judgments, assumptions, and uncertainties associated with their critical accounting estimates and outline factors that are subject to variability. They should explain which factors are subject to change the most and their relative sensitivity to change as well as discuss factors that can cause changes.

As before, the SEC stressed the disclosure of all critical accounting estimates, including the following:

- Methods and assumptions behind fair value calculations
- Estimation of common stock fair value
- Policy for valuation of warrants and other complex equity instruments
- Measurement of different kinds of liabilities
- Determination of enterprise value
- Calculation of transaction price based on Accounting Standards Code (ASC) 606
- Classification of revenue components under contracts with customers with requisite disclosures
- Treatment of milestone royalty payments and other revenue streams and costs under different types of agreements
- Basis of presentation and consolidation among wholly owned subsidiaries, controlled entities, and variable interest entities

A majority of IPO applicants were asked to disclose differences between the fair value of their common stock leading up to the IPO and the estimated offering price to clarify their accounting for equity issuances, cheap stock, and stock-based compensation.

In cases that used non-US generally accepted account principles (non-GAAP) financial measures, registrants were asked to meet all disclosure requirements as under Item 10(e) of Regulation S-K.

The crux of this topic is to make sure companies carefully design their accounting policies in accordance with authoritative guidance, implementing them consistently and disclosing them thoroughly in public filings.

Investors need to understand the principles, assumptions, methodology, and limitations, if any, before they can fully deduce the meaning behind results. The key for registrants, like every period, will be to make explicit disclosures that, while preventing repetitiveness, promote a meaningful analysis of measurement, risks, and uncertainties.

Sample Comments

> *We note your disclosure that you estimated the value of the shares of common stock issued for services using the asset approach. Please tell us how you determined the asset approach was appropriate given the cash transactions for shares of common stock.*

> *Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.*

> *Please expand your disclosure to include the valuation methodologies used by the independent third-party valuation firm to estimate your total equity value along with the nature of material assumptions used within those methodologies. If more than one methodology is used, provide a discussion of the weighting of those methodologies.*

LIQUIDITY AND CAPITAL RESOURCES

Disclosure of adequate liquidity and capital resources remains an important element within MD&A, being mandated under Item 303(b)(1) of Regulation S-K.

Comments in this topic made up 11.4% of total MD&A comments in 2021–2022, up from 4.2% in the previous report.

Focus remained on requiring registrants to be more precise in discussing their funding obligations, including accounting for any uncertainties. They were asked to provide adequate detail as to their plans to finance certain large-scale capital expenditures, describe payment obligations under various agreements, and present assurance that they have sufficient funds to run operations for at least the next 12 months.

These disclosures became especially pertinent when auditors had expressed doubt in their report about the company's ability to continue as a going concern.

While the percentage of comments in this subcategory are relatively low every period, the comments are significant. A change in the number of comments for a particular category shouldn't be construed as a reflection of its importance. A declining number of comments may merely suggest companies are taking better steps to cover all the aspects in their filings, leaving little room for further scrutiny.

Sample Comments

> *We note your intention to build additional greenhouses on your properties that will include a research and development facility. Please provide a discussion of your material known or anticipated capital expenditures and other investments that includes quantified information for the costs of these capital projects and how you intend to finance these projects. Refer to Item 303(b)(1)(ii)(A) of Regulation S-K for guidance.*

> *Please revise your liquidity disclosures to address the Tax Receivable Agreement, disclosing your estimates of annual payments and how you intend to fund the required payments under the agreement. In this regard, we note your statements that you expect the future payments under the agreement may be substantial. This information should also be disclosed in the Summary and in the Risk Factors.*

> *Please provide the basis for your statements that you "expect to generate revenue that is sufficient to cover [y]our expenses for the next twelve months" and that "[y]our existing sources of liquidity will be sufficient to fund [y]our operations, anticipated capital expenditures, working capital and other financing requirements for at least the next twelve months." In this regard, we note that your independent auditor's report contains an explanatory paragraph that expresses substantial doubt about the Company's ability to continue as a going concern.*

RESULTS FROM OPERATIONS

Comments related to operational results made up 22.7% of total MD&A comments this period, slightly up from 16.7% in 2020–2021.

Given the nature of the MD&A section, the presentation and discussion of results is a critical element, the absence of which can lead to ambiguity and a lack of understanding of the companies' financial status and results.

Similar to each period, the SEC emphasized the importance of disclosing material changes in operational metrics on a granular level and outlining the impact on revenue and expense streams.

Registrants were asked to provide a more detailed analysis for each material quantitative change in operating measures from period to period, which included identifying and possibly quantifying all company-driven factors and market forces that caused those changes.

They were also asked to discuss and analyze any known material trends, events, demands, commitments, uncertainties, and related underlying reasons or drivers with respect to such changes. A prime example of this is COVID-19, the impact of which has been mixed at varying magnitudes across life sciences companies.

Some registrants were also asked to expand their disclosure of results for different operating segments, especially where sales in foreign markets constituted a significant portion of revenue.

The recent amendments have further streamlined disclosure of operational results, reiterating the importance of disclosing material information and factors. SEC scrutiny is expected to continue, making sure registrants include materiality in the prospectus.

Sample Comments

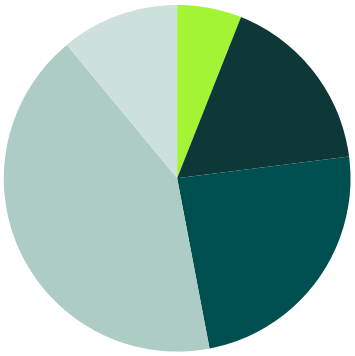
> *Please revise your discussion of revenues throughout this section to discuss, and where possible quantify, the changes in your revenues resulting from changes in prices, changes in volume or a combination of both items. Please refer to Item 303 and the related instructions in Regulation S-K as well as SEC Interpretive Release No. 33-8350.*

> *We note your disclosure of the impact of the COVID-19 pandemic on your company, and also the seasonality of your main product, [product name]. We also note the patent protection for [product name] expired in early 2019. Revise your disclosure related to the impact of the pandemic to provide additional insight as to why you believe your product sales declines related to the pandemic rather than other factors, such as increased competition from generic products. For example, clarify whether sales increased in the fourth quarter of 2020 and first quarter of 2021, as the pandemic restrictions eased in some areas.*

> *Given the significance of the items included within your other income and expenses to your operations, please include a table disaggregating such items to complement the period-to-period change explanations. This comment applies to both your interim and annual disclosures.*

SEC REPORTING

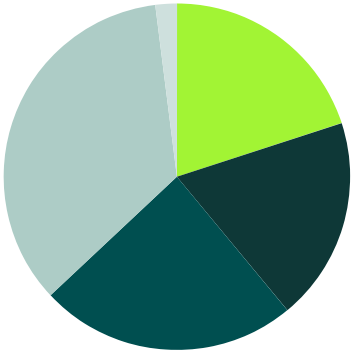
FIGURE 11: Number of Comments for Form S-1
By SEC Reporting Subcategory



2020-2021

6%	Acceptance of Liability
17%	Discrepancies
24%	Filing of Exhibits and Other Material
42%	Updated Disclosures
11%	Other

161 Total Comments



2021-2022

20%	Acceptance of Liability
19%	Discrepancies
24%	Filing of Exhibits and Other Material
35%	Updated Disclosures
2%	Other

155 Total Comments

Process compliance is critical for any business ecosystem, whether expanding into new markets, products, or financing routes. Meeting compliance and disclosure metrics is extremely important, especially for Form S-1 registrants drafting their first IPO disclosures.

Registrants receive many comments on their Form S-1 filings requiring them to add or modify disclosures. This can be as simple as providing the relevant exhibits, updating financial statements, or adding in the right number of signatures, pursuant to Regulation S-K and Regulation S-X requirements.

Even though comments here are generally formulaic in nature, they do make up a sizeable volume every year. Companies shouldn't overlook the importance of process requirements, which can cause filing and transaction delays.

The SEC's modernization drive included a few recent amendments, with the objective to make compliance metrics filer- and investor-friendly. An August 2022

amendment dealing with pay versus performance disclosure rules is one of many proposed changes. Recent regulatory dynamism, with many new measures under development, includes bringing attention to ESG disclosures and transparency to cybersecurity issues.

Companies must stay abreast of regulatory developments and make sure their filings meet current standards. SEC scrutiny emphasizes the need for active and alert compliance.

Comments related to process compliance totaled 155 this period, making up 10.4% of total Form S-1 comments. While this is a slight decline from a share of 11.3% in the previous report, this category continued to make up the third largest category of comments for Form S-1 filings.

Like every year, the SEC required registrants to undertake a significant number of changes in the prospectus and make updated disclosures.

These included areas such as:

- Accepting accountability for information presented in the filing
- Correcting discrepancies throughout the statement
- Filing relevant exhibits and other material

ACCEPTANCE OF LIABILITY

Comments directed toward ensuring companies' acceptance of liability jumped over 244%— in absolute terms—from the previous report. A total of 31 comments in this topic made up 20% of the process compliance mix in 2021–2022, significantly up from a share of 5.6% in 2020–2021.

Registrants may use external data sources and statistics to support a prospectus but must verify those statements are reliable for investors.

The SEC frequently emphasizes to registrants that they're responsible for the entire contents of the registration statement, and any cautionary language suggesting otherwise prompts comments and needs to be revised.

In this period's comments, the SEC reiterated that liability to registrants, especially in sections containing industry and market data or forward-looking statements.

Many companies acknowledged that they hadn't independently verified information from third-party publications or studies, and no independent source verified their internal research and results. Some even explicitly asked investors not to give undue weight to such estimates.

The SEC asked those companies to revise the statements and remove any disclaimer, and specifically note the registrant's liability.

Registrants were told to revise any disclaimer language regarding forward-looking statements, too.

Companies must assume due responsibility in preparing a registration statement, which is information for the public. Readers rely on it to make crucial investment decisions.

Sample Comments

> *You state that you have not independently verified market and industry data from third party sources, nor have you ascertained the underlying economic assumptions relied upon therein, and that you believe your internal research is reliable, even though such research has not been verified by any independent sources. You also caution potential investors not to give "undue weight" to such estimates. These statements appear to imply a disclaimer of responsibility for this information in the registration statement. Please note that you are responsible for the entire contents of the registration statement. Please*

> *either revise this section to remove such implication or specifically state that you are liable for all information in the registration statement.*

> *We note your statement that certain information contained in the prospectus involves a number of assumptions and limitations, and investors are cautioned not to give undue weight to such estimates. Please revise to remove any implication that investors are not entitled to rely on the disclosure in your registration statement.*

> *You state on [page reference] that investors are cautioned not to "place undue reliance on" statements that reflect your intentions and expectations disclosed in forward-looking statements. Please note that you are responsible for the disclosure contained in your registration statement and you may not use language that could be interpreted as a disclaimer of information contained in your filing. Please revise.*

DISCREPANCIES

A document as large as a prospectus with multiple sections and filings has the potential for inconsistencies or discrepancies. Errors can be as simple as inputting different values for the same information in different parts of the statement, missing a decimal point, or a typo.

Sometimes these discrepancies can stem from conflicting facts. Many registrants may have a characterization in one section that is portrayed differently in another. For example, if a company says it completed Phase II trials for a specific product candidate in their pipeline table, but the business section says only Phase I is complete, the inconsistency confuses the reader and invites SEC comment.

This period, comments related to discrepancies made up 18.7% of total process compliance comments, representing an increase from a share of 17.4% in the previous report.

As in every year, discrepancies arose in a variety of areas. This ranged from disclosures regarding the following:

- Products in development
- Clinical trials
- Commercialization strategy
- Nature of entity operations
- Employment agreements
- Compensation
- Outstanding debt and equity securities
- Share conversion terms
- Ownership percentages
- Intellectual property rights
- Election under the JOBS Act
- Nature of accounting policies adopted
- Exclusive forum provisions

Cross-checking for consistency across the document is critical to keep all disclosures coherent and keep SEC comments at bay. Simple and inadvertent errors can sometimes create a mountain of scrutiny and revision.

Sample Comments

> *Your disclosure that you are a "development stage" company contradicts your disclosure on [page reference] that you are a clinical stage company. Please revise.*

> *We note your statement that you have had no operating losses since inception. The statement appears to contradict the net operating losses [dollar value] and [dollar value]*

> *for the years ended March 31, 2020, and 2021. respectively. Please revise your disclosure accordingly.*

> *Here and in a risk factor at [page reference], you state you have elected to take advantage of the extended transition period for complying with new or revised accounting standards under Section 107(b) of the JOBS Act. However, your disclosure on [page reference] states that you have irrevocably elected not to avail yourselves of this exemption from new or revised accounting standards. Please correct these apparent inconsistencies. If you elect to opt out of these provisions, please indicate as such on the cover page.*

FILING OF EXHIBITS AND OTHER MATERIAL

For applicants filing on EDGAR for the first time, providing key information as exhibits and reference documents is pivotal. Every year, this area continues to be of considerable significance for Form S-1 filers.

Comments related to filing exhibit material made up 23.9% of total process compliance comments this period, slightly down from a share of 24.2% in 2020–2021.

Similar to the previous period, comments here were standardized and procedural in nature, requiring companies to comply with all exhibit guidelines as stipulated in Item 601 of Regulation S-K.

This section lists all documents that need to be filed with Form S-1 plus those that may be incorporated by reference. These include acquisition and reorganization plans, articles of incorporation, contractual arrangements, and expert opinions and consents, among others.

Materiality is a key word in deciding what to file and what may be omitted. Registrants must file documents pertaining to all material agreements or arrangements referred to in the statement or otherwise provide an analysis of why they believe such arrangements aren't material enough to be included as an exhibit.

In cases with redacted confidential information, companies should include a statement on the first page of the exhibit that certain identified information has been excluded from the exhibit because it's both not material and is also the type that is treated as private or confidential. They must also include brackets indicating where the information is omitted from the filed version of the exhibit.

Sample Comments

> *Please file your Lease Agreement for your [facility name] and the [dollar value] Promissory Note as exhibits pursuant to Item 601(b)(s10) of Regulation S-K.*

> *We refer to the [entity name] Asset Purchase Agreement filed as [exhibit reference] to your registration statement. We note that certain identified information has been redacted in this exhibit as noted in the exhibit index. Please revise the first page of the exhibit to include a statement that certain identified information has been excluded from the exhibit because it is both not material and is the type that you treat as private or confidential. Please also include brackets indicating where the information is omitted from the filed version of the exhibit. Refer to Item 601(b) of Regulation S-K.*

> *Please file a tax opinion as an exhibit to the filing or provide us with your analysis as to why the tax consequences of the Up-C reorganization transactions are not material to an investor, and therefore no tax opinion is required to be filed. Refer to Item 601(b)(8) of Regulation S-K and Section III.A.2 of Staff Legal Bulletin 19.*

UPDATED DISCLOSURES

Similar to every report, a considerable number of process compliance comments were directed at the broad subcategory of updated disclosures, which requires registrants to update information throughout the prospectus and also provide greater clarity in certain areas.

Comments in this area made up 35.5% of process compliance comments this period, down from 41.6% in 2020–2021.

Companies were asked to make revisions such as:

- Update financial statements and provide financial statement significance calculations
- Update the cover page to provide cross referencing to different sections
- Furnish full disclosures as per Item 701 of Regulation S-K, recent sales of unregistered securities
- Complete the capitalization table to reflect all balances
- Ensure any disclosure qualified by reference has the relevant information included in the prospectus
- Fill in missing material information and disclosures erroneously left blank
- Double check all intended sections are present in the document itself

Within this, a key area of focus was on exclusive forum provisions. Companies were asked to clarify whether the provision applied to actions arising under the Securities Act or Exchange Act and state this clearly in the prospectus.

There's no formula for avoiding this scrutiny, but some steps registrants can take include:

- Proactively double-check the prospectus to make sure disclosures are complete and without gaps
- Ensure facts and figures have been updated
- Review past comment trends to identify and rectify common mistakes

Sample Comments

> *Please update the cover page of your registration statement to include a highlighted cross reference to the risk factors section. Refer to Item 501(b)(5) of Regulation S-K.*

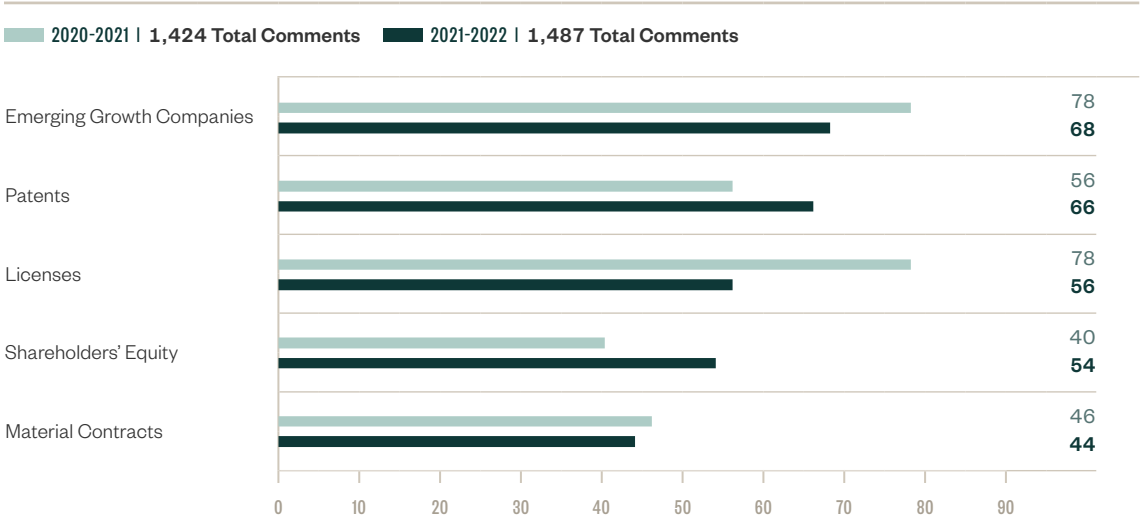
> *Please confirm that you will update your disclosure for any shares you become obligated to issue under the Stock Purchase Agreement prior to the completion of the initial public offering.*

> *Please update the documents incorporated by reference to include the quarterly report on Form 10-Q for the quarter ended March 31, 2021.*

> *We note that the forum selection provision in your bylaws identifies the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation, including any "derivative action." Please disclose whether this provision applies to actions arising under the Securities Act or Exchange Act. In that regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. If the provision applies to Securities Act claims, please revise your prospectus to disclose this information and to state that there is uncertainty as to whether a court would enforce such provision, and to state that stockholders will not be deemed to have waived the company's compliance with the federal securities laws and the rules and regulations thereunder. If this provision does not apply to actions arising under the Securities Act or Exchange Act, please also ensure that the exclusive forum provision in the governing documents states this clearly.*

OTHER DISCLOSURE TOPICS

FIGURE 12: Number of Comments Related to Other Disclosure Topics for Form S-1



A wide range of other topics were covered in SEC comments directed at Form S-1 filings in 2021–2022, including comments related to the following:

- Emerging-growth company (EGC) status
- Patents
- Licensing agreements
- Shareholders' equity
- Material contracts

Together, these comprised over 19% of total Form S-1 comments.

EMERGING GROWTH COMPANIES

The JOBS Act intended to help small businesses go public under emerging-growth company (EGC) status. This status allows them to have less-expansive disclosures than required of non-EGC candidates and defer compliance with certain accounting standards.

Typically, a company retains EGC status for the first five fiscal years after completing an IPO, unless one of the following occurs:

- Its total annual gross revenues are $1.07 billion or more
- It issued more than $1 billion in nonconvertible debt in the past three years
- It becomes a large-accelerated filer, as defined in Rule 12(b)-2 of the Exchange Act

A total of 68 comments related to EGCs constituted 4.6% of the Form S-1 comments in 2021–2022, a slight decrease from 5.5% in 2020–2021. The SEC continued to ask registrants to provide copies of all written communications, as per Rule 405 of the Securities Act, and requested them to clarify their EGC status and elections.

Sample Comments

> *Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.*

> *At this time, you must make your choice whether to opt out of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the Jobs Act. Please revise your disclosure on [page reference] to disclose your election under Section 107(b) of the Jobs Act:*
>
> - *If you have elected to opt out of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the Jobs Act, include a statement that the election is irrevocable; or*
> - *If you have elected to use the extended transition period for complying with new or revised accounting standards under Section 107(b) of the Jobs Act, expand your risk factor on [page reference] to explain that, as a result of this election, your financial statements may not be comparable to companies that comply with public company effective dates. Include a similar statement in your critical accounting policy disclosures in your MD&A.*

PATENTS

Given the time- and capital-intensive nature of the life sciences industry, the SEC places emphasis on intellectual property rights every year.

Comments related to patents made up 4.4% of total Form S-1 comments in 2021–2022, registering an increase from 3.9% in the previous report.

The nature of disclosure required was again largely standardized, with companies expected to identify the number of patents held and applied for clearly in the prospectus. The SEC then required registrants to revise their intellectual property discussion to disclose, for each material patent and patent application, the following parameters:

- Specific products or technologies to which such patents or patent applications relate to
- Type of patent protection granted for each product or technology on an individual basis, such as for composition of matter, use, or process
- Whether the patents are owned or licensed
- Expiration dates
- Applicable jurisdiction, including any foreign jurisdiction, of each pending or issued patent

The SEC encouraged registrants to use tables to support the discussion and help prevent ambiguity on each patent and patent application's individual characteristics.

Similar disclosure was required for any patents to be filed, with companies providing anticipated as opposed to actual expiration dates.

The SEC also focused on discussing competitive position. Some companies were asked to revise their discussion of competitive conditions by describing in detail the current industry landscape for patent protections. This included detailing any risks associated with securing patent protection and any impact associated with existing third-party patents or patent applications.

Sample Comments

> *Please revise to disclose for each material patent and patent application the expiration dates and applicable material jurisdictions, including any foreign jurisdiction. Please also disclose whether you intend to file additional patent applications and include, to the extent known, the specific product(s) to which such patent applications would relate, the type of patent protection, the expiration dates, and the applicable material jurisdictions, including foreign jurisdictions.*

> *Please revise your intellectual property disclosure to clearly describe on an individual or patent family basis the type of patent protection granted for each product, the expiration year of each patent held, and the jurisdiction of each patent. Please clearly distinguish between owned patents and patents out licensed to third parties. In this regard it may be useful to provide tabular disclosure.*

> *Please specifically disclose each of the "25 additional countries worldwide" in which you have granted patents and/or pending patent applications and the expiration date of these international patents and/or pending patent applications.*

LICENSES

Entering into license agreements continues to be a major strategy among life sciences players, helping them reduce developmental costs, save time, share risks, and synergize on expertise.

However, this category saw less focus this period compared to the last. Comments related to licenses made up 3.8% of the Form S-1 mix in 2021–2022, dropping from a share of 5.5% in the previous report.

The nature of comments remained consistent year over year. The SEC required registrants to disclose key contractual terms for each of their license agreements, which included details such as:

- Nature, scope, and ownership of transferred intellectual property
- Each party's rights and obligations
- Duration of the agreement
- Royalty term
- Royalty range, not exceeding 10 percentage points
- Expiry of the last-to-expire patent licensed
- Type of payments involved, such as quantification of any upfront fees, aggregate amounts paid or received to date, and any aggregate future amounts to be paid or received under each agreement.
- Trigger events
- Termination provisions

To the extent material, some registrants were also required to file the license agreements as an exhibit, pursuant to Item 601(b)(10) of Regulation S-K.

Registrants must be precise in their disclosures and present each of their agreements with full clarity to investors, including any risks or contingencies involved.

Sample Comments

> *Please revise this section to disclose aggregate potential milestone payments segregated by development, regulatory and commercial sales milestones. Where applicable, disclose the royalty rate or range not to exceed ten percentage points per tier. Additionally, please disclose the royalty term, duration of the agreement and termination provisions.*

> *Please revise your disclosure concerning the [party name] license agreement to disclose the expected expiry of the last-to-expire patent licensed under the agreements or the expected last-to-expire payment obligations.*

> *We note your description of your [party name] agreement. Please revise to clarify what you mean by "lower double digits to the lower teen digits" so that investors understand the potential range of royalty payments in a range not to exceed ten percent. If the range is more than ten percent, please provide a range within ten percent for each tier or disclose the number of tiers.*

SHAREHOLDERS' EQUITY

The nature and composition of shareholders' equity is a core pillar underpinning a company's capital structure. It largely governs both interest and control dynamics, which has a critical part to play in the direction of the firm and is of intense investor focus. Consequently, the need to make unambiguous disclosures here is unparalleled.

Comments related to shareholders' equity made up 3.6% of total Form S-1 comments this period, registering an increase from a share of 2.8% in 2020–2021.

The SEC's scrutiny continued to focus on the following key parts of equity:

- Beneficial ownership percentages
- Rights governing each class of shares,
- Share issuance price and underlying value
- Conversion terms of convertible classes
- Effects of dilution

The SEC emphasized investment-related disclosures this period. A number of registrants identified certain entities in the prospectus as investors that didn't appear among the principal stockholders. The SEC asked the registrants to expand such disclosure, if material, and describe the nature of each such entity's investment in them. This also included explaining their plans to update investors about any changes these entities make with respect to their investments.

Sample Comments

> *Please separately disclose the number of shares of common stock issued for services and for cash, including the value of the shares issued for services and the amount of cash received, respectively.*

> *We note that you identify certain entities as investors in your company here and on [page reference]. However, certain of these entities do not appear to be among your principal stockholders as disclosed on [page reference]. If material, please expand your disclosure to describe the nature of each such entity's investment in you and explain to us why including this information is appropriate. Please also explain in the response your plans to update investors about any changes these entities make with respect to their investments in your company.*

> *Please revise the footnotes to your table to identify the natural persons who are the beneficial owners of the shares held by the 5% or greater stockholders.*

MATERIAL CONTRACTS

A company's material contracts are those key agreements that outline its strategic collaborations, alliances, and significant partners for fundamental operations. The nature of these can range from product development to exclusive licensing agreements, dominant supplier and distribution relations, funding grants, and a lot more.

Firms might have operational dependency on fulfillment of certain contracts, or base their competitive advantage on them, making those contracts material and inherently critical to the company.

Disclosure of these material contracts is paramount. Comments related to this topic made up roughly 3% of total Form S-1 comments in 2021–2022, staying in line with the previous report.

Similar to previous years, the SEC asked registrants to fully describe all agreements that were material to the company, which included highlighting the significant terms of each of these agreements and filing them as exhibits pursuant to Item 601(b)(10) of Regulation S-K.

Disclosure of significant terms, like license agreements, largely revolved around the following parameters:

- Parties' rights and obligations
- Financial terms, including all amounts paid to date
- Aggregate milestone amounts to be paid or received
- Royalty range and term
- Term of agreement and termination provisions
- Any amendments, if carried out, to agreement terms

Materiality is the main question. Are registrants not classifying certain agreements as material that are important to the company? The SEC raised this issue several times in its comments, asking registrants why they had not thoroughly described or filed certain important agreements in their statement.

While this classification of materiality is based on judgment, there should be a standardized rule of thumb to avoid under-reporting. Ultimately, any agreement that affects or can significantly affect metrics—such as revenue, cost, intellectual property, or developmental pipelines—should be described as being material.

While the SEC's modernization amendments reduced the burden of reporting certain information that may be competitively sensitive, they don't remove the onus on filers to disclose all information that's material to investors.

Sample Comments

> *We note your response to comment 13 and do not agree that this agreement is not required to be filed as an exhibit to your registration statement. Specifically, we note that the agreement provided you with an upfront payment of [dollar amount] in funding of your product candidates in exchange for licensing rights related to one of your product candidates. It appears that you are substantially dependent on funding provided from the agreement and your future development of [candidate name] may be dependent on potential milestone payments related to regulatory achievements made by [party name].*

> *Please include disclosure in the Business and the MD&A sections to include the material terms of the master services agreement with [party name]. We refer to your disclosure on [page reference] but did not note any further references in the prospectus. Please also file the master services agreement as an exhibit to the registration statement as required by Item 601(b)(10) of Regulation S-K or tell us why you believe you are not required to do so.*

> *On [page reference] you state that the majority of your clinical trials have been funded by grants awarded by the NIA. Please revise [page reference] to describe the terms of such grants and the other grants listed on [page reference]. To the extent you have an agreement with NIA, tell us your basis for deciding not to file any agreement with NIA as an exhibit pursuant to Item 601(b)(10) of Regulation S-K.*

Trends in Forms 10-K, 10-Q & 20-F Filings

Overall, comments directed toward Forms 10-K, 10-Q, and 20-F made up roughly 8% of the total 1,625 comments analyzed in 2021–2022, which was an increase from a 5% share in 2020–2021.

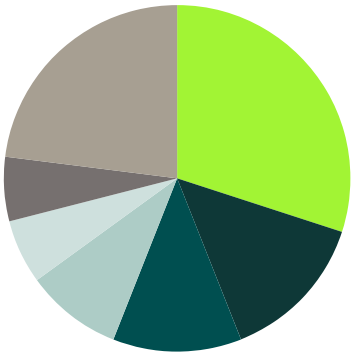
Topics such as MD&A, process compliance, and R&D remained in focus while entity-related disclosures saw a significant rise in comments. Together, these made up 90 of the total 138 comments.

Disclosure of risks and internal control over financial reporting (ICFR) stood next in line, capturing 11.6% of the share together.

The remaining comments were spread over other categories in a marginal-to-negligible share of these filings.

Unlike its Form S-1 scrutiny, the SEC placed focus on companies' operational activities, results, and developmental expenses, requiring consistent disclosures across filings. Even in entity-related disclosures, there was greater emphasis put on companies' legal structure and related regulatory and operational implications.

FIGURE 13: SEC Comment Categories for Forms 10-K, 10-Q, and 20-F Filings

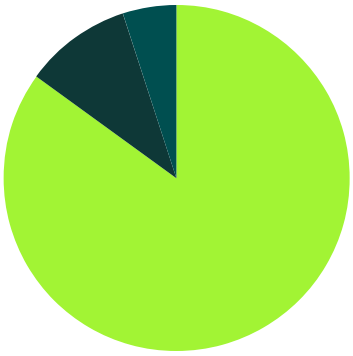


2020-2021

30%	Management's Discussion and Analysis
14%	SEC Reporting
12%	Entity Background
9%	Research and Development
6%	Disclosures About Risk
6%	Internal Control Over Financial Reporting
23%	Other Comments

138 Total Comments

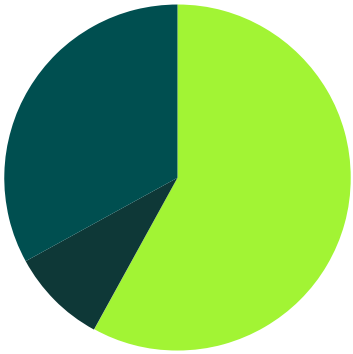
FIGURE 14: Breakdown of Forms 10-K, 10-Q and 20F Comments
By Filing Type



2020-2021

85% Form 10-K
10% Form 10-Q
5% Form 20-F

73 Total Comments



2021-2022

58% Form 10-K
9% Form 10-Q
33% Form 20-F

138 Total Comments

Form 10-K submissions attracted the greatest SEC scrutiny among all the three filings in 2021–2022, constituting 58% of the total 138 comments. Comments on Form 20-F earned 33% and Form 10-Q filings earned the remaining 9%.

This is a change from the previous study. The skew in SEC comments toward Form 10-K eased and there's a greater share on Forms 10-Q and 20-F this period. Within this, Form 20-F was the second largest filing type by total number of comments, more than Form 10-Q.

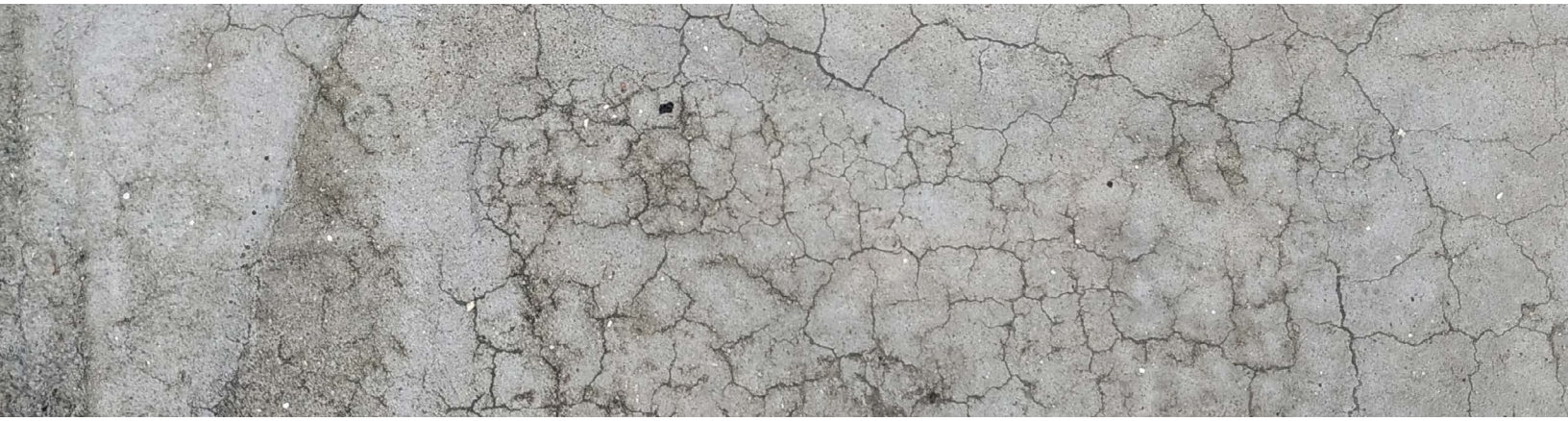


FIGURE 15: Key Areas of SEC Focus for Forms 10-K, 10-Q, and 20-F Filings
By Number of Comments

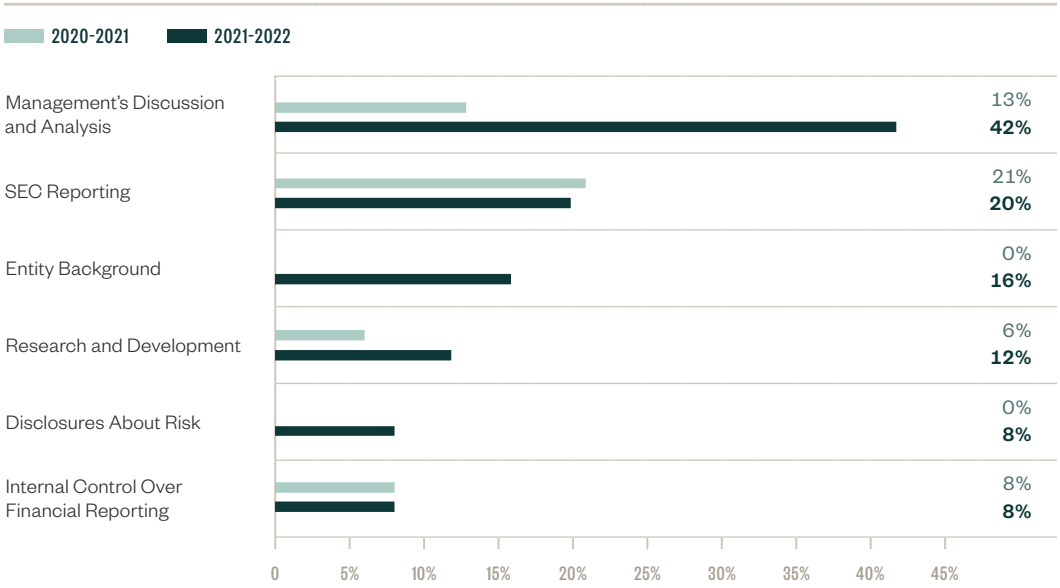
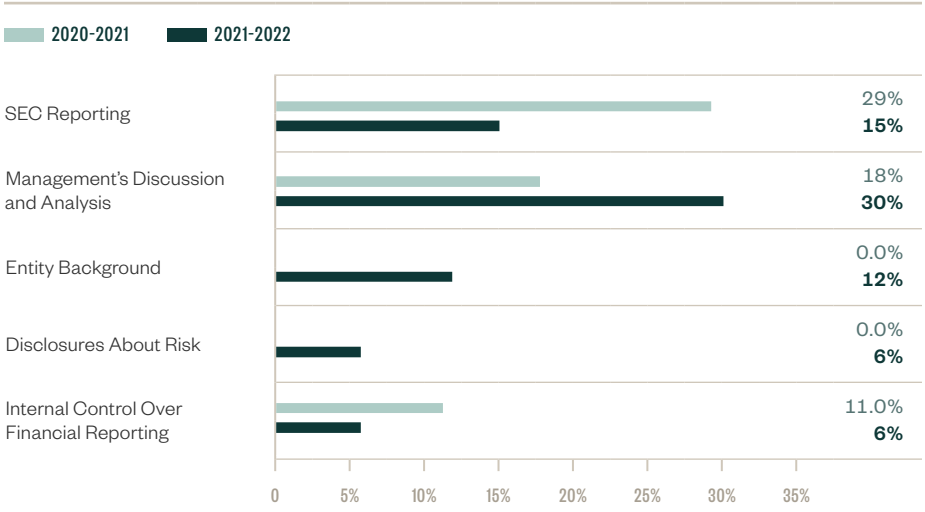


FIGURE 16: Significant Shifts in SEC Focus for Forms 10-K, 10-Q, and 20-F Filings
By Ratio of Comments



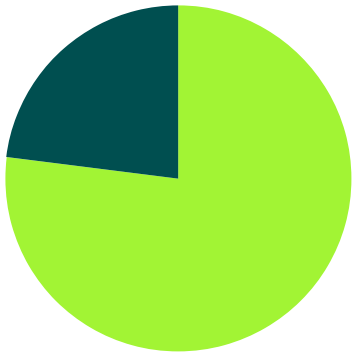
SEC scrutiny around MD&A grew 12.6% compared to 2020–2021. Entity-related and risk-based disclosures, which saw no comments in the last study, accounted for a share of 11.6% and 5.8%, respectively.

Focus on process compliance and ICFR dropped by 14.3% and 5.2%, respectively.

These shifts shouldn't be seen as a guide for what's important to cover in filings. For example, a drop in comments related to process compliance doesn't imply there's less need for disclosure on this subject. A declining number of comments may be the result of companies making improvements in their filings and disclosures.

MANAGEMENT'S DISCUSSION & ANALYSIS

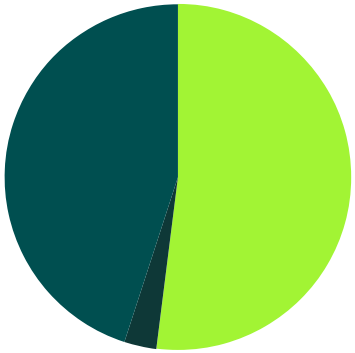
FIGURE 17: Number of Comments for Forms 10-K, 10-Q, and 20-F Filings
By Management's Discussion and Analysis Subcategory



2020-2021

77%	Critical Accounting Policies
0%	Liquidity and Capital Resources
23%	Results From Operations

13 Total Comments



2021-2022

52%	Critical Accounting Policies
3%	Liquidity and Capital Resources
45%	Results From Operations

42 Total Comments

Comprehensive disclosures of operational performance year-over-year is important for both pre-IPO candidates and post-IPO filers. Regardless of how long a company has been in the public domain and making recurrent filings, its business environment continues to change. Companies must account for such external changes, coupled with internal dynamics, that drive both current and future results.

The recent amendments to Item 303 of Regulation S-K helped streamline such disclosures under MD&A, providing filers with more flexibility as to the presentation and discussion of all material elements unique to their case. The goal is to present information in the most complete, precise manner that meets the SEC's requirements under consideration of materiality yet eliminates redundancy and complexity.

Comments related to MD&A made up 30.4% of the 138 comments directed toward these filers in 2021–2022, registering a significant increase from a share of 17.8% in the previous study.

Similar to the previous study, the SEC required companies to provide a detailed discussion of any material changes in operational results and present a quantified analysis of significant factors that led to changes.

Such factors can include external drivers such as supply chain disruptions, pandemic-related arrangements, generic competition, and internal fluctuations such as the impact of acquisitions, weakening of customer credit, manufacturing defects, or similar.

The key here is identification, quantification, and discussion. Companies must communicate fluctuation in core metrics like revenue, cost, and expenses in a way that investors can understand the magnitude and relative impact of each factor.

The disclosure of critical accounting policies is particularly important for helping investors understand the context behind numerical results. The SEC required companies to provide their accounting methodology for all core operational parameters, citing the authoritative literature on which they relied.

Such parameters included, among others:

- Treatment of sales discounts and pricing
- Cost of inventory, including zero-cost inventories
- Identification and amortization of intangibles
- Allocation of line items in merger and acquisition transactions
- Classification of gains and losses
- Absorption of accounting losses
- Use of non-GAAP financial measures, including compliance with Item 10(e) of Regulation S-K

Given the depth, breadth, and criticality of disclosures under MD&A, SEC scrutiny here is high and companies are encouraged to address and clarify ambiguity in their statements.

Sample Comments

> *We note the statement on [page reference] that certain product promotions including discounted products and customer incentive promotions are recorded as part of Associate incentives within operating expenses. Please describe these product promotions in greater detail. Explain to us why you are accounting for these product promotions as operating expenses, citing the applicable accounting literature. Describe to us why these product promotions are not accounted for under ASC 606 as an adjustment to the transaction price as variable consideration.*

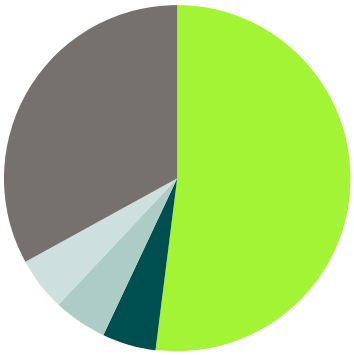
> *We reference your disclosures attributing material fluctuations in your revenues, costs, and expenses to multiple factors. In future filings, please quantify each factor cited so that investors may understand the magnitude and relative impact of each factor. For example, you should quantify the impact of material acquisitions on revenue and costs of revenues as well as the amount of revenue loss attributed to terminated contracts. Also consider providing revenue fluctuations by product or product grouping. In addition, future filings should separately quantify research and development expenses by each product candidate for which significant investments were made during the periods. Refer to Item 303(b) of Regulation S-K.*

> *You disclosed here that the increase in the [revenue type] service revenue was due to the Covid-19 related contracts and arrangements. Considering the significance of this item in 2020 and for the six months ended June 30, 2021, tell us how you have considered compliance with the disclosure requirement under Item 303 of Regulation S-K, which requires the disclosure of any significant components of revenues or expenses that, in the registrant's judgment, should be described in order to understand the registrant's results of operations, as well as any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. Please include revised disclosure to be included in future filings.*

> *Please explain why bad debt expense increased by [percent value] whereas net receivables decreased by [percent value]. Any material changes in the aging of receivables and/or the credit quality of major accounts should be clearly disclosed.*

SEC REPORTING

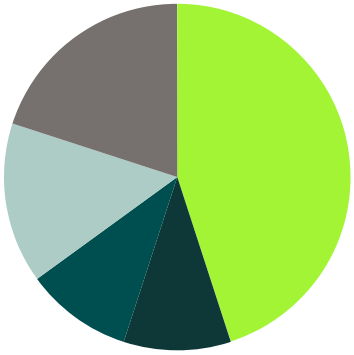
FIGURE 18: Number of Comments for Forms 10-K, 10-Q, and 20-F Filings
By SEC Reporting Subcategory



2020-2021

52%	Certifications
0%	Discrepancies
5%	Filing of Exhbits and Other Material
5%	Other
5%	Signatures
33%	Updated Disclosures

21 Total Comments



2021-2022

45%	Certifications
10%	Discrepancies
10%	Filing of Exhbits and Other Material
15%	Other
0%	Signatures
20%	Updated Disclosures

20 Total Comments

Comments related to process compliance decreased from a share of 28.8% of these filings in 2020–2021, to 14.5% this period.

Most comments focused on certifications. Companies were largely required to revise their Section 302 certifications to include the introductory language in paragraph 4 referring to their ICFR as well as paragraph 4(b), which referred to the design of internal reporting.

Filers were also required to file complete Section 906 certifications or revise their existing certifications to comply with specifications under Item 601 of Regulation S-K.

Other comments requiring disclosures focused on the following areas:

- Filing of requisite exhibit material
- Reconciling discrepancies among different filings or auditor's report
- Revising financial statements to correct for accounting errors
- Updating procedural elements like the cover page

The drop in comments doesn't signify any change in importance of process compliance. It may show that companies strove for better compliance with procedural rules, inviting fewer comments in this area.

Sample Comments

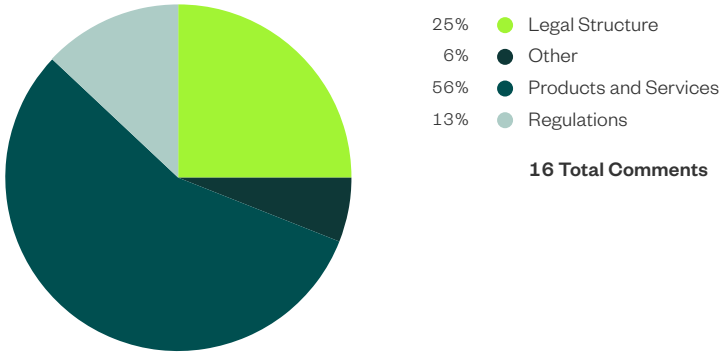
> *We note that you filed your Principal Executive Officer and Principal Financial Officer certifications under Item 601(b)(31) of Regulation S-K. Please amend the Form 20-F to revise the certifications to include the introductory language of paragraph 4 to reference your internal controls.*

> *Please amend your Form 10-Q for the six months ended June 30, 2021, and your Form 10-K/A for the period ended December 31, 2020, with complete Section 302 certifications that reference internal control over financial reporting in the headnote to paragraph 4.*

> *Please amend your Form 10-Q for the quarter ended June 30, 2021, to address the following:*
>
> - *Revise Additional paid in capital, Accumulated deficit, and Total stockholders' equity (deficit) for the period ended June 30, 2020, on your Condensed Consolidated Statements of Stockholders' Equity (Deficit) to reflect the accounting error related to the June 2020 forbearance agreements. Refer to [Note] in your Form 10-K.*
> - *Label both 2020 columns as being restated.*
> - *Provide disclosures related to the restatement.*
> - *Disclose, if true, that the net loss per common share for the three and six months ended June 30, 2020, have been revised to reflect the stock split.*

ENTITY-RELATED INFORMATION

FIGURE 19: Number of Comments for Forms 10-K, 10-Q, and 20-F Filings
By Entity Related Subcategory | 2021-2022



Comments directed toward entity-related disclosures grew from zero last period to 11.6% of these filings this time.

The SEC focused on companies' existing products and services, as with Form S-1 registrants. This mainly pertained to Form 20-F filers, where the SEC required them to disclose the following parameters and provide greater information about their operations:

- Nature of offerings and implication of government regulations in a particular segment

- Role of different stakeholders in the business model
- Geographical spread of all manufacturing facilities
- Degree of volatility in raw material procurement
- Inventory shelf life
- Principal market channels being used, or intended to be used, to generate sales
- Types of expansion strategies pursued

Legal structure and consequential regulatory implications for certain entities was an area of focus. All legal structure comments were directed at one company in the United States with operations conducted outside the country through subsidiaries, and contractual arrangements with variable interest entities.

The SEC was primarily concerned with ensuring adequate and transparent disclosures relating to legal structure to allow investors to assess risk when it comes to holding equity interests. Such companies need to clearly disclose the regulatory scope for not just its holding entity but operational entities as well, describing how operations are conducted within its large network.

All filers must be detailed when describing the nature of their unique business model and operations, presenting both the strengths and risks in a balanced manner.

Sample Comments

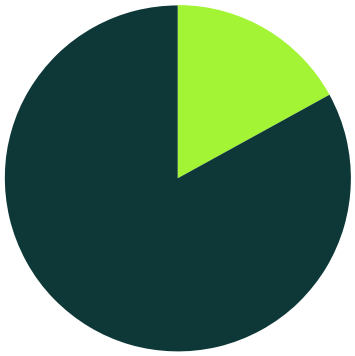
> *Please expand your discussion in Information on the Company section to disclose the nature of your operations activities involving [the Company's] products as well as describing the material effects of government regulations on this aspect of your business.*

> *Please expand your disclosure to describe the principal marketing channels you use or intend to use, including an explanation of any special sales methods.*

> *Explain whether the VIE structure is used to replicate foreign investment in [country-based] companies where [foreign country] law prohibits direct foreign investment in the operating companies, and disclose that investors may never directly hold equity interests in the [foreign] operating company. Your disclosure should acknowledge that [foreign] regulatory authorities could disallow this structure, which would likely result in a material change in your operations and/or value of your common stock, including that it could cause the value of such securities to significantly decline or become worthless. Provide a cross-reference to your detailed discussion of risks facing the company as a result of this structure.*

R&D

FIGURE 20: Number of Comments for Forms 10-K, 10-Q, and 20-F Filings
By R&D-Related Subcategory



2020-2021

17%	Clinical Trials and Studies
83%	Expenses
0%	FDA Filings and Communications
0%	Products and Services

6 Total Comments

2021-2022

8%	Clinical Trials and Studies
76%	Expenses
8%	FDA Filings and Communications
8%	Products and Services

12 Total Comments

R&D was the fourth largest category this period with a share of 8.7% of these filings. In comparison to the previous study, its significance to filers remained intact.

Most of the SEC's focus again was placed on expenses. Many companies were asked to elaborate on the nature of R&D expenses incurred each year, disaggregate expenses by product or program type, and explain significant fluctuations.

The remaining comments were regarding clinical trials, developmental products, and FDA communications, asking companies to be more specific in their disclosures. This included disclosing whether trials are meeting their endpoints, the regulatory status of upcoming products including the risks they may pose, and the status of approval reviews.

Sample Comments

> *Please disclose the costs incurred during each period presented for each of your key research and development projects. If you do not track your research and development costs by project, please disclose that fact and explain why you do not maintain and evaluate research and development costs by project. Provide other quantitative or qualitative disclosure that provides more transparency as to the type of research and development expenses incurred (i.e., by nature or type of expense) which should reconcile to total research and development expense on the Consolidated Statements of Operations.*

> *Please specify which of your planned products are those which you note "are subject to legalization and/or obtaining necessary additional licenses."*

> *Please disclose the timeline of the planned and current clinical trials. If you have received results from any trial, please clarify whether or not the trial achieved its primary and secondary endpoints.*

OTHER DISCLOSURE TOPICS

RISK DISCLOSURES

Comments related to risk-based disclosures made up 5.8% of total comments in these filings in 2021–2022, a significant rise from no comments last period.

Much of the focus was placed on companies disclosing all legal and operational risks, especially those with complex structures involving variable interest entities in foreign locations. This included, among others, risks related to regulatory changes, sanctions, or management and control, which can change the nature or value of securities held by investors.

Other comments were, as before, similar to those for Form S-1 registrants, especially those directed toward Form 20-F filers. The SEC asked companies to be very specific in their risk factor disclosure and outline all risks pertaining to operations.

Sample Comments

> *Revise your risk factors to acknowledge that if the [foreign country] determines that the contractual arrangements constituting part of your VIE structure do not comply with [their] regulations, or if these regulations change or are interpreted differently in the future, your shares may decline in value or become worthless if you are unable to assert your contractual control rights over the assets of your [foreign] subsidiaries that conduct a significant portion of your operations.*

> *Revise this risk factor or include a new risk factor to clarify, if true, that your products have not yet been distributed through any of your partnerships and that none of your partnerships are currently operational.*

INTERNAL CONTROL OVER FINANCIAL REPORTING

ICFR is a critical factor that maintains the credibility of financial statements and promotes information transparency. It's codified under Item 308 of Regulation S-K, which outlines management's responsibility and annual disclosure requirements around the same.

The number of comments related to ICFR remained the same over the last two years, but made up 5.8% of these filings this period, a drop from 11% in 2020–2021.

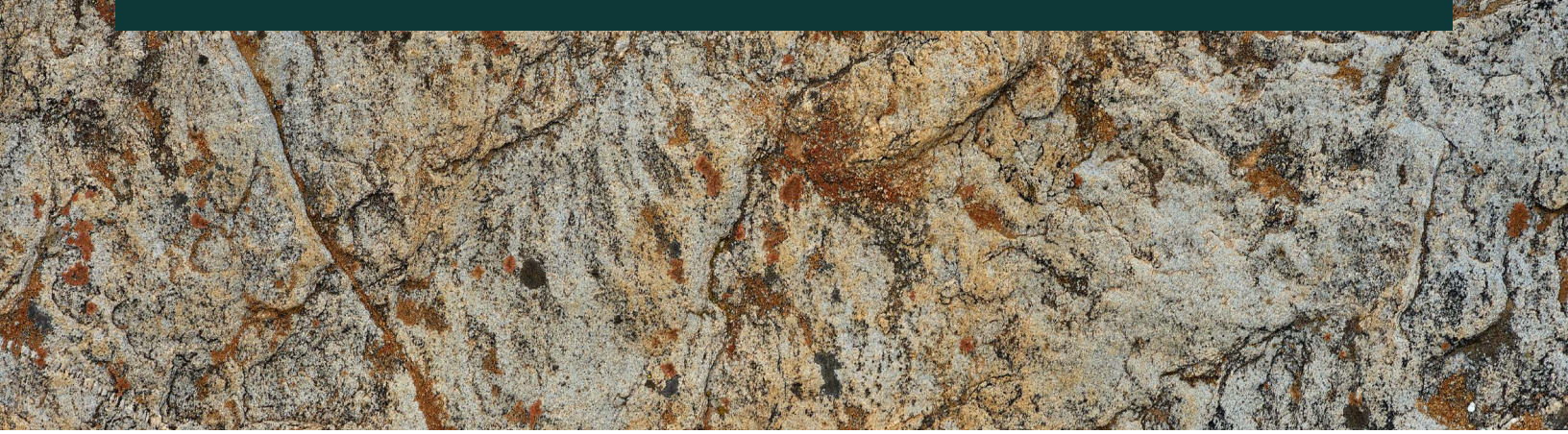
Similar to the previous study, the SEC asked companies to make requisite disclosures when it comes to management's annual report on ICFR, pursuant to Item 308(a) of Regulation S-K. This included outlining the framework management used to evaluate the effectiveness of ICFR and providing a definitive conclusion as to their effectiveness in accordance with Items 308(a)(2) and 308(a)(3) of Regulation S-K.

In case of material weaknesses or ineffectiveness of ICFR, companies were asked to clearly describe the steps they took toward remediation and the status of those plans to enhance ICFR.

Sample Comments

> *We note that you included management's assessment of the effectiveness of internal control over financial reporting and that you have a material weakness over your entity level control environment; however, your report does not include a statement as to whether or not internal control over financial reporting is effective as required by Item 308(a) of Regulation S-K. Please amend your Form 10-K to include a statement as to whether or not ICFR is effective at March 31, 2021. Additionally, in your revised disclosure please provide a discussion of your remediation plan to address any material weaknesses.*

> *Within management's assessment of disclosure controls and procedures, we note that you identify material weaknesses within the Company's internal control over financial reporting. Item 308(a)(3) of Regulation S-K prohibits management from concluding internal control over financial reporting is effective when one or more material weaknesses exist. However, you state management determined that you maintained effective internal control over financial reporting at December 31, 2020. Please amend the filing to comply with Item 308(a)(3) of Regulation S-K or explain to us why no such revision is required.*



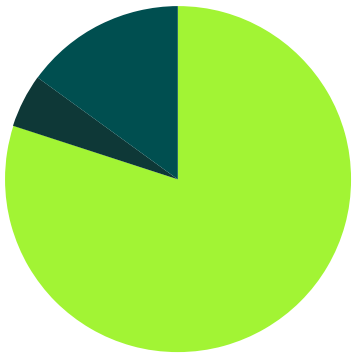
MARKET CAPITALIZATION RANGE

The scope of this analysis focused on smaller companies with market capitalizations of less than $2 billion.

Over 73% of Forms 10-K, 10-Q, and 20-F comments centered on companies with a market capitalization of less than $500 million. Of the remaining, 10% were directed toward those with market capitalization between $500 million and $1 billion while 17% pertained to those greater than $1 billion but less than $2 billion.

Smaller companies continued to attract the greatest scrutiny.

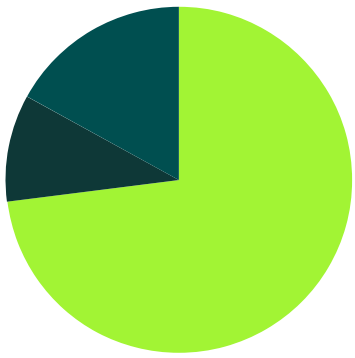
FIGURE 21: Breakdown of Forms 10-K, 10-Q, and 20-F Comments
By Market Capitalization Range ($B)



2020-2021

80%	$0.00 – 0.50
5%	$0.51 – 1.00
15%	$1.01 – 2.00

73 Total Comments

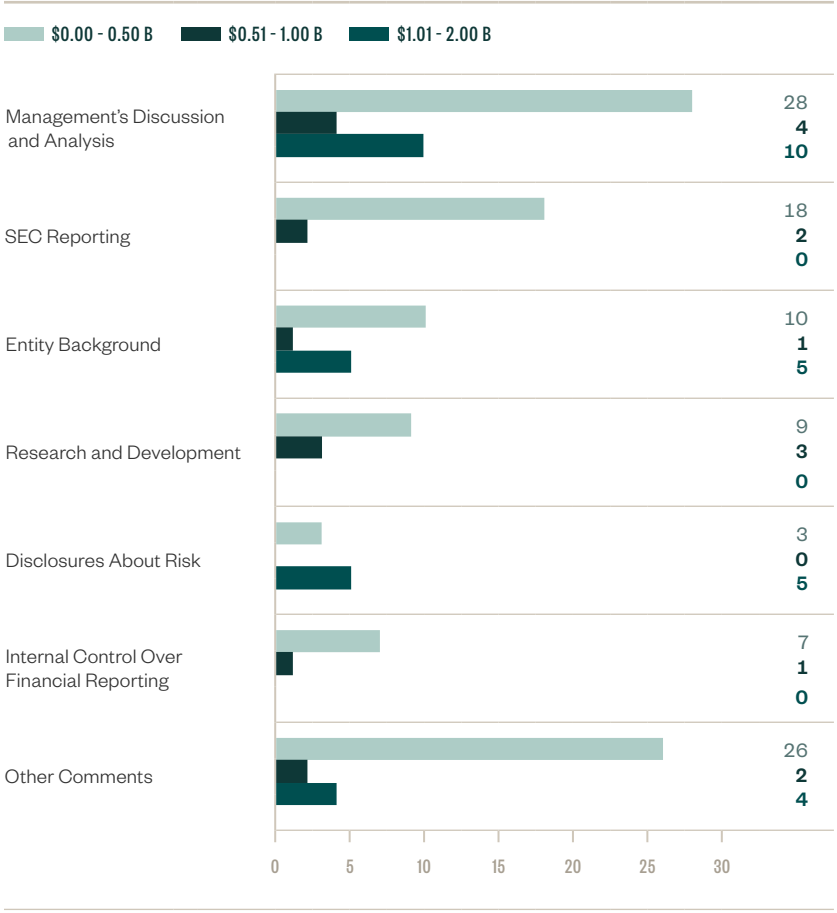


2021-2022

73%	$0.00 – 0.50
10%	$0.51 – 1.00
17%	$1.01 – 2.00

138 Total Comments

FIGURE 22: Trends in SEC Comment Categories by Market Capitalization
2021-2022 by Number of Comments



Similar to previous years, company size and the extent of SEC scrutiny continued to have a negative correlation; the number of comments decreased as market capitalization increased. There was a slight increase in comment count in $1 billion to $2 billion companies this period mainly related to one company.

Despite this, the negative correlation held and can be mainly attributable to a difference in experience and resources. Registrants filing statements for the first time might not be well-versed in regulatory compliance and can attract more SEC comments and require more iterations before getting the process right.

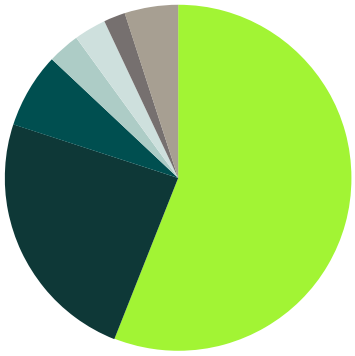
Smaller companies have fewer resources to allocate toward compliance than larger capitalized companies which might have more experience and in-house processes for maintaining compliance.

The current market-cap distribution among life sciences companies indicates there may be a greater number of small-sized players than larger ones, which also impacts the distribution of SEC comments to each category.

Regardless of size, building a thorough understanding of the SEC's disclosure standards will help facilitate a smoother filing process for all companies.

Subindustry Trends

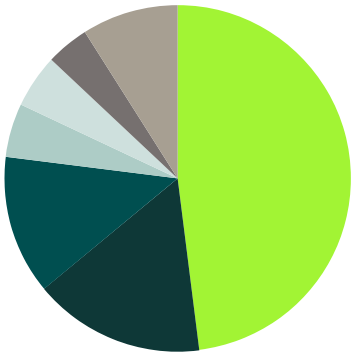
FIGURE 23: Percentage of Comments
By Subindustry



2020-2021

56%	Pharmaceutical Preparations
24%	Biological Products (No Diagnostic Substances)
7%	Surgical and Medical Instruments and Apparatus
3%	Medicinal Chemicals and Botanical Products
3%	Laboratory Analytical Instruments
2%	Commercial Physical and Biological Research
5%	Other Subindustries Combined

1,497 Total Comments



2021-2022

48%	Pharmaceutical Preparations
16%	Biological Products (No Diagnostic Substances)
13%	Surgical and Medical Instruments and Apparatus
5%	Medicinal Chemicals and Botanical Products
5%	Laboratory Analytical Instruments
4%	Commercial Physical and Biological Research
9%	Other Subindustries Combined

1,625 Total Comments

Pharmaceutical preparations continued to attract much SEC focus. While its share of total comments decreased from 55.8% in 2020–2021 to 47.9% this period, its significance in relation to all other subindustries is intact. The majority of the Forms S-1, 10-K, 10-Q, and 20-F filings studied in this analysis were from companies in pharmaceutical preparations.

Generally, companies in this subindustry are defined as primarily engaged in "manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use." This includes a wide product portfolio that's largely intended for final consumption, including "ampoules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions."

Given this broad spectrum of activities, which consists of extensive clinical research, long product development periods, and complex intellectual property rights, the extent of compliance checks and disclosure required can be significant. While this consideration applies to all registrants, such responsibility becomes

more onerous for Form S-1 registrants and IPOs that have a larger disclosure scope to meet in the first place.

Biological products was the next most significant subindustry with an aggregate comment share of 15.9%, followed by surgical and medical instruments and apparatus at 13.2%.

As in previous years, there has been a shift in dynamic between these two categories. While the ratio of comments for surgical and medical instruments and apparatus went up by 5.9% from the previous study, that for biological products came down by 7.8%. This pattern of increase and decrease occurred for the last three consecutive periods.

Medicinal chemicals and botanical products was the subindustry with the fourth largest comment share with 5.2%. SEC focus increased from the previous report.

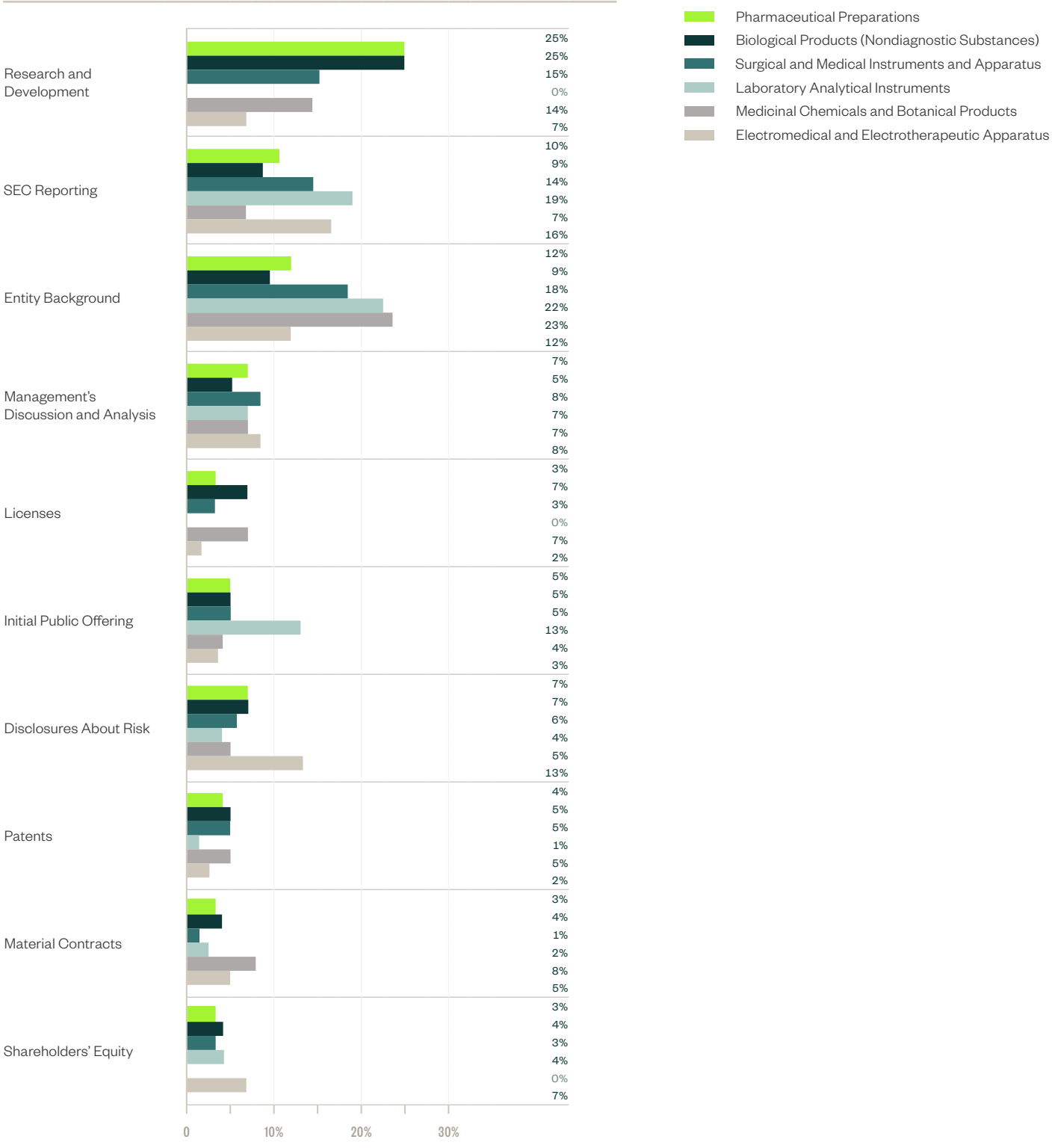
Other subindustries had smaller shares of less than 5% each.

Ophthalmic goods and dental equipment and supplies, which didn't attract any relevant comments in 2020–2021, made up 44 and 18 comments this period, respectively.

NATURE OF COMMENT CATEGORIES

While all subindustries are essentially part of the life sciences sector, they differ on an individual basis in their activities, corresponding value chains, and business models. This can make them subject to varied regulations and operational parameters, attracting a slightly different SEC focus.

FIGURE 24: Share of Comment Categories
2021-2022 by Subindustry



Compliance is a critical cornerstone for every company in the life sciences industry. Making even a simple filing mistake or disclosure error can attract scrutiny.

Consequently, comments related to process compliance remained significant across subindustries, generally making up 10%–15% of the mix.

R&D, always an area of focus for life sciences, has a slightly skewed subindustry spread when it comes to the number of SEC comments. Subindustries such as pharmaceutical preparations and biological products see a much higher number of comments year-over-year.

This can stem from complex development pipelines, involving many clinical studies and long gestation periods. Companies are required to make expansive disclosures around such activities and any missing components can prompt comments.

Comments related to R&D in the pharmaceutical preparations and biological products subindustries made up almost 25% of the mix.

Meanwhile, entity-related disclosures made up a large portion of SEC comments for surgical and medical instruments and apparatus as well as laboratory analytical instruments. This trend has stayed consistent year-over-year. On the other hand, medicinal chemicals and botanical products saw a jump in entity-related disclosures this period, with comments in this area making up 22.4% of the mix.

Certain topics may attract more scrutiny one year and less the year after. For example, companies in laboratory analytical instruments saw much less focus on process compliance this period than in the previous report, while comments related to R&D increased.

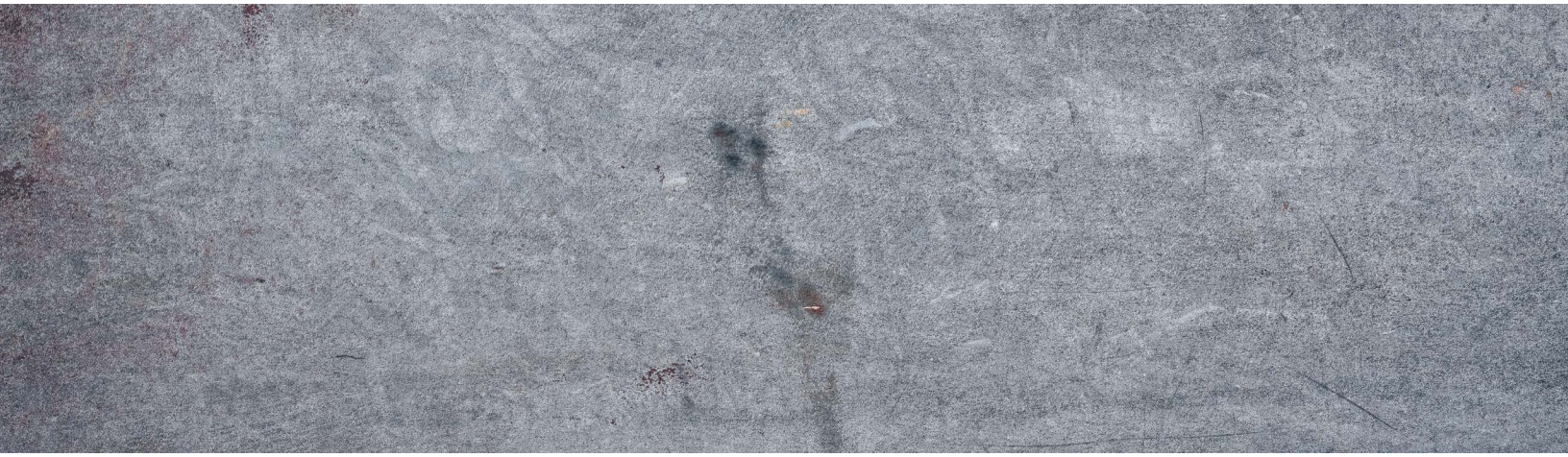
Commercial physical and biological research had more process compliance comments this period, but comments for MD&A reduced at a similar rate.

Some topics remain common for an entire sector, and others will continue to vary among subindustries. Even within a subindustry, some categories may attract greater scrutiny in one particular year and less the next.

This depends on both market dynamics and timing, which may bring certain issues to the forefront and highlight efforts companies are making to properly address these areas in their filings.

Companies need to stay abreast of market specifics, paying close attention to inherent challenges or sensitivities that may require additional clarification. They also need to monitor changing macro-conditions on both global and local levels, understanding effects on business and whether they require further disclosure.

Information clarity and transparency remain critical at all points during this process.



SECTION FIVE

Conclusion

Industry focus is shifting from the pandemic to holistic health care solutions. Whether it be rolling out new drugs, concentrating on mobile-health wearables, or creating service-oriented clinical programs, new projects abound.

The race toward breakthrough therapies for chronic and unmet diseases is on and companies are working to make the most of this opportunity.

Increasing R&D budgets, creating strategic alliances, working on licensing networks, and partnering with medical professionals continue to be key strategies.

Common objectives are to cut costs, share risks, and reduce the R&D period to meet demand for such therapies as quickly as possible while keeping patient safety paramount.

IPOs continue to be a core part of the operational roadmap as they open financing avenues and invite investor support.

SEC COMPLIANCE TRACKER

Maintaining sound regulatory compliance can drive operational efficiency and reduce procedural delays.

Maintaining compliance includes staying up to date with SEC standards and requirements, which are applicable from the first IPO registration statement through all subsequent required public filings.

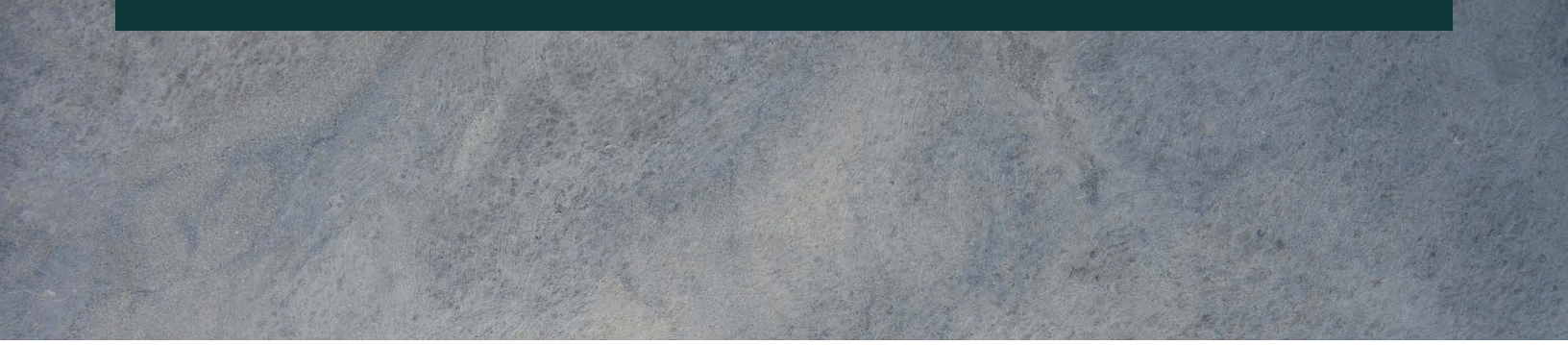
Companies can benefit from the following steps:

- Create informative and sound documents
- Provide clear and adequate disclosures on all critical matters
- Keep investor confidence intact

With IPOs expected to remain a strong and viable financing source in the life sciences domain, it's more important than ever to understand and adhere to filing guidelines.

It's always beneficial for companies to proactively identify particular areas of interest or focus in their filings that may attract SEC scrutiny. This scrutiny generally varies according to company size, form and filing type, and the nature of operation.

As observed in the 2021–2022 report, the SEC sought clarity from companies on a host of issues, ranging from adequate disclosures and insightful discussions to clear presentation of information in filings.



POPULAR TOPICS

R&D, process compliance, and entity-related disclosures generate the most SEC scrutiny year-over-year. Because life sciences companies deal with significant research costs, developmental cycles, product pipelines, and regulations, disclosure in these areas is important.

Communicating complex operational structures and companies' business models for investors is pivotal, especially for registrants going public for the first time.

SEC comments aren't limited to Form S-1 registrants. Discussions of operational results, key business risks, and management outlook are among the many topics that attract SEC scrutiny for all SEC registrants every year.

All these disclosures must be made within stipulated SEC guidelines. Adherence to Regulation S-K and Regulation S-X remains pivotal and can be as fundamental as including the right signatures or filing the right documents.

WHY IT MATTERS

Knowing what's important—and why—matters. Getting the process right the first time saves time and resources, enabling a smooth flow of operations.

This report focuses on familiarizing life sciences companies with pertinent factors in their registration statements and filings by discussing comments the SEC made. It applies not only to the middle-market companies included in the scope of this analysis, but all current and future registrants.

Insights from these generic trends, coupled with guidance from specialist advisors, can help companies anticipate and avoid obstacles. Preventing simple mistakes can in turn save time and money.

THE ROUTE TOWARD SEC PREPARATION

Familiarize yourself with the purpose of SEC filing and take note of designated forms	*Identify patterns* in SEC comments, assessing those made for similar filings in the past
Understand your industry and requisite value chain of activities that need attention	*Analyze trends* to understand salient features that must be accounted for
Know where you fit in terms or the filing requirements and relevant procedures	*Get in touch* with specialist advisors for doubts and customized solutions

WE'RE HERE TO HELP

If you want more insight into the SEC's comment process or you have questions on how to prepare your company for its IPO, contact a Moss Adams professional.

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