MOSSADAMS

Under the Microscope

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

2022-2023

CONTENTS

INDUSTRY OVERVIEW

The dry spell in initial public offering (IPO) activity that started in 2022 continued into the period under scrutiny in this report: May 2022 through April 2023 (2022 and 2023), leading life sciences companies to develop new financing strategies to remain viable. Yet, there seems to be light at the end of the tunnel heading into 2024.

PERFORMANCE RECAP

Deal activity cascaded drastically over the last two years, with the global IPO market falling by 94% from calendar year 2021, as per Fenwick & West's IPO market review. Proceeds in life sciences transactions decreased by over $50 billion from the 2021 highs near $70 billion amid tight capital market conditions, rising interest rates and tumbling valuations. There were no life sciences direct listings in 2022, while the number of de-SPAC (special purpose acquisition company) transactions stood at 23.

Life sciences companies have started using new financing mechanisms, which includes evaluating the private fundraising sector, innovative forms of debt financing, implementing operational cost-cuts, and active management to reduce cash outflows, as well as scouting for strategic alliances and collaborations to share costs.

Many later-stage growth companies with revenues have become more prudent in their approach and are striving to balance product investment with operational profitability to become cash-flow positive. Earlier-stage growth companies that are pre-Food and Drug Administration (FDA) approval have also become more frugal in their research and development approach in order to extend their cash runway.

Macroeconomic conditions in the marketplace, like rising interest rates, inflationary pressures on costs, financial market instability, together with a strong US dollar and relatively weaker global currencies, also continue to strongly influence companies' financial strategies and impact financial performance.

This isn't to say that conventional markets won't rebound. Investors are optimistic that better days are ahead, with complete IPO recovery and momentum expected to gradually pick up in 2024. While a 2021-like boom is unlikely, a growth in deal count and size is expected. Mid-size companies offering stable returns appear to be poised to dominate the market. Winners will be those businesses with a defined product pipeline and concrete focus on target indications, a feasible development plan, and a comprehensive route for final commercialization, which together will bring investor confidence back.

At the same time, maintaining dynamic business models that are ready to pivot with change will become critical. Given the sudden outbreak of the Israel-Hamas conflict, along with the Russia-Ukraine war, it's fair to say that uncertainty from geopolitical tensions will continue to be a factor.

Investors will need transparency that companies acknowledge these inherent risks and have plans in place to address them.

KEY INDUSTRY TRENDS

While activity in life sciences has largely normalized in 2023, the demand for research and development (R&D) and lab-testing remains above levels seen before the COVID-19 pandemic. In fact, with the range of construction projects currently underway, total life sciences lab and R&D space can grow by more than 20% over the next two years, as per CBRE's industry outlook.

The sector started the year with record-high employment, although the rate of growth was subdued compared to previous periods. Prospects are bright for the addition of value-added, new-gen roles in the coming years, with the FDA recognizing an increased usage of artificial intelligence (AI) and machine learning throughout the drug development life cycle and in a range of therapeutic areas.

The level of industry growth is dependent on a lot of other factors as well, especially on whether the threat of an economic recession can be negated, and financial markets can be revived with stability. Having said that, it's important to note, as the previous two years have gone to show, the life sciences sector is far more resilient to withstand these challenges in comparison to many others.

Realistic R&D

The FDA approved 37 novel drugs in 2022, as well as previously approved drugs in new settings, such as for new indications and patient populations. While infectious diseases such as COVID-19, HIV, or smallpox continued to remain a key target, modalities for neurological conditions, endocrine diseases, autoimmune and inflammatory conditions, as well as cancer, were highly sought after.

Numerically, there's a downward trend in new drug approvals, showing a significant decline from 50 drugs approved in 2021. As the effects of the COVID-19 pandemic fade, the associated frenzy over new and fast cures has subsided. The FDA is looking for concrete long-term solutions backed by systematic clinical trials and results. Life sciences companies are encouraged to harness technology to create efficient and effective developmental procedures that are ambitious and innovative yet realistic enough to culminate in a product.

These dynamics were observed in the 2022–2023 SEC filings, with R&D, which has always been a key topic of focus, continuing to come under intensive scrutiny.

In most of the filings studied that were Form S-1 prospectuses, the emphasis on making adequate disclosures and clarifications in a range of R&D areas—drug development, clinical trials, pipelines, and current and upcoming products—remained paramount.

Transparent and Balanced Disclosures

Information accuracy, clarity, and transparency remain of utmost importance, especially in an industry like life sciences that operates in a stringent regulatory environment. Companies need to be cautious in their description of both product candidates and finished products, avoiding misleading claims. Such disclosures are critical in public filings and prospectuses leading up to an IPO.

Like previous periods, SEC examination of information symmetry, adequacy, and effectiveness continued to be a key focus in 2022–2023, with many registrants

asked to reevaluate the language used in their statements—especially related to product description, efficacy, and market standing.

Meanwhile, those already in the public domain were asked to be highly transparent when discussing operational results and specifically state the legal and structural ramifications tied to them.

The SEC is further enacting new rules that emphasize increased transparency. Disclosure of information pertaining to share transactions has widened, with the SEC in May 2023 adopting amendments to modernize and improve disclosure about repurchases of an issuer's equity securities, which includes requiring issuers to provide daily repurchase activity on a quarterly or semi-annual basis, depending on the type of issuer. The goal is to increase clarity and provide investors with enhanced information to assess the purposes and effects of share repurchases.

Cybersecurity-related disclosures are also growing. In July 2023, the SEC adopted rules requiring registrants to disclose material cybersecurity incidents they experience and to disclose, on an annual basis, material information regarding their cybersecurity risk management, strategy, and governance. Foreign private issuers are required to make comparable disclosures.

In the advent of growing digital operations posing an increased risk to sophisticated cybercrime, the nature of these disclosures is likely to grow and be standardized.

Extended ESG

Making climate-related disclosures and addressing relevant risks is no longer voluntary but a legal requirement in many countries. Investors are showing interest in environmental, social, and governance (ESG) factors, especially as governments undertake large-scale reforms to meet carbon neutrality goals.

The SEC has proposed rule changes that would require registrants to include certain climate-related disclosures in their registration statements and periodic reports, including climate-related risks that are reasonably likely to have a material impact on their business, results of operations, or financial condition, and certain climate-related financial statement metrics in a note to their audited financial statements. A registrant's greenhouse gas emissions, which is a key assessment metric, would also need to be disclosed.

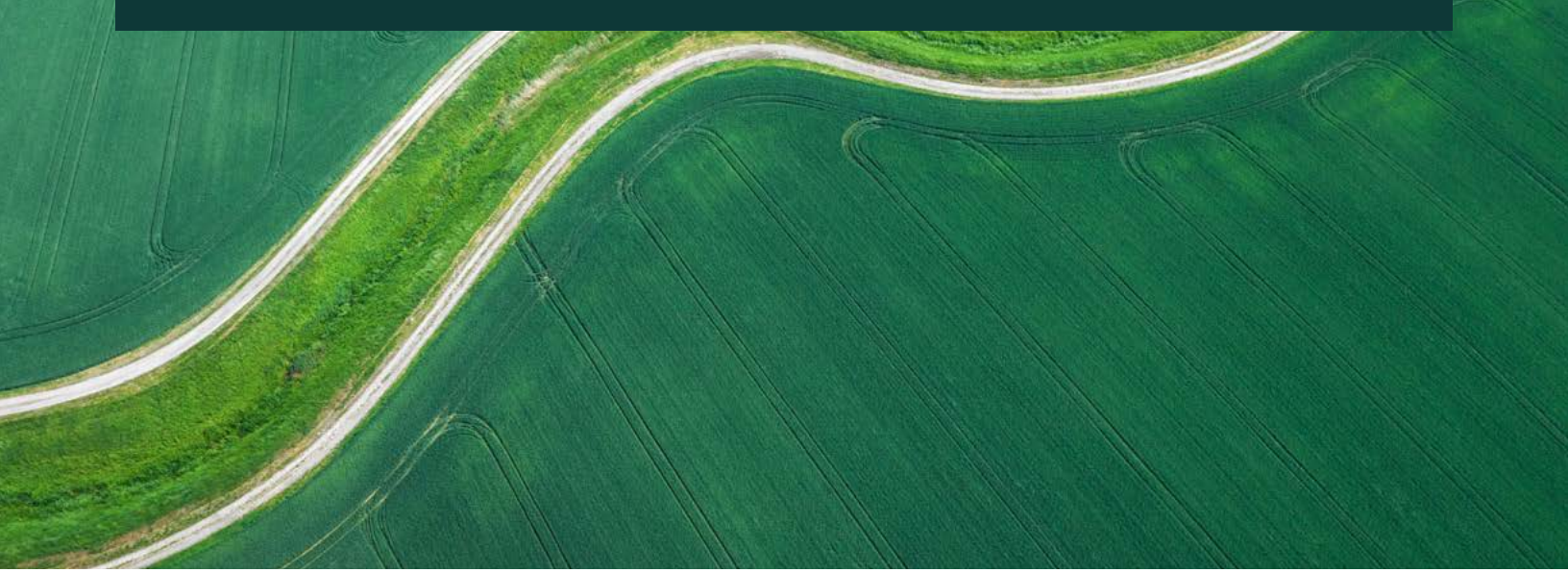
Companies can use this lean IPO period to become IPO-ready by conducting a comprehensive climate-risk assessment across their business processes and ensuring accountability for disclosure.

As per Fenwick & West's IPO market survey, 50% of life sciences investors believe the role of ESG in IPO valuations and investment decisions is very important, while 44% of life sciences executives have implemented ESG initiatives or have a plan in place for the same.

Managing Changing Procedural Requirements

Changing trends and issues play into changing regulations. The SEC's various amendments and proposals reflect their efforts to keep up with dynamic market conditions. The goal 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 2022–2023, identifying possible patterns, and changes in SEC staff focus in relation to the 2021–2022 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 included 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 comments related to companies with market capitalization greater than $2 billion on the dates of analysis, which were August 19–20, 2023.

Our analysis included comments filed on the SEC EDGAR database during the period from May 1, 2022, to April 30, 2023, which we'll refer to as 2022–2023.

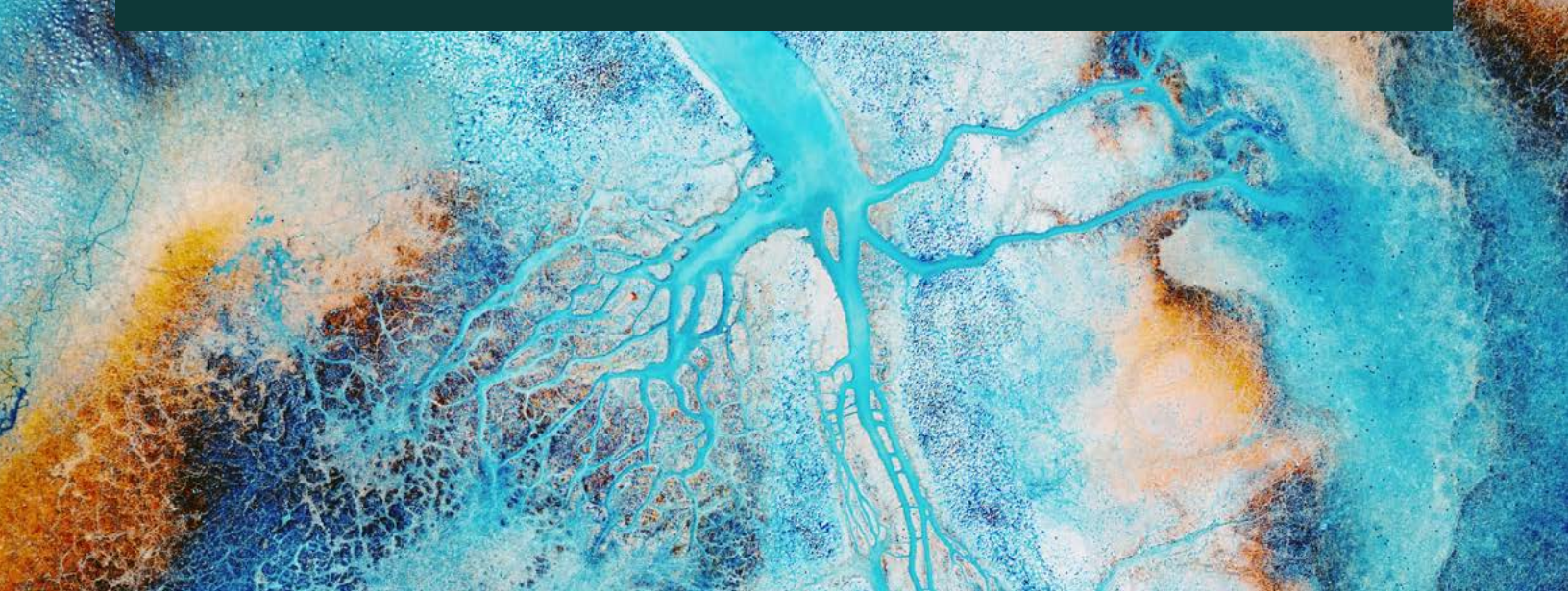
To achieve a fair and objective assessment of the data, we considered only the first instance of an SEC comment letter for an individual filing, given that in subsequent instances letters from the SEC often contained comments of similar nature to those found in the first iteration, or enhanced the previous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

While the period of analysis under our current and previous reports, known as 2022–2023 and 2021–2022, 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 2021–2022 to 2022–2023 exceeded the mean variance in that subset to be significant variances over the last two years.

For example, out of the 1,487 comments directed toward Form S-1 filings in 2021–2022, 89 were related to IPOs, amounting to a ratio of approximately 6%. The same ratio increased to roughly 10% in 2022–2023, an increase of approximately 4%. 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 initial public offering-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 693 comments were issued in response to Forms S-1, 10-K, 10-Q, and 20-F filings in 2022–2023, a substantial decrease from a high comment count of 1,625 in 2021–2022, as consistent with the overall decrease in IPO filings.

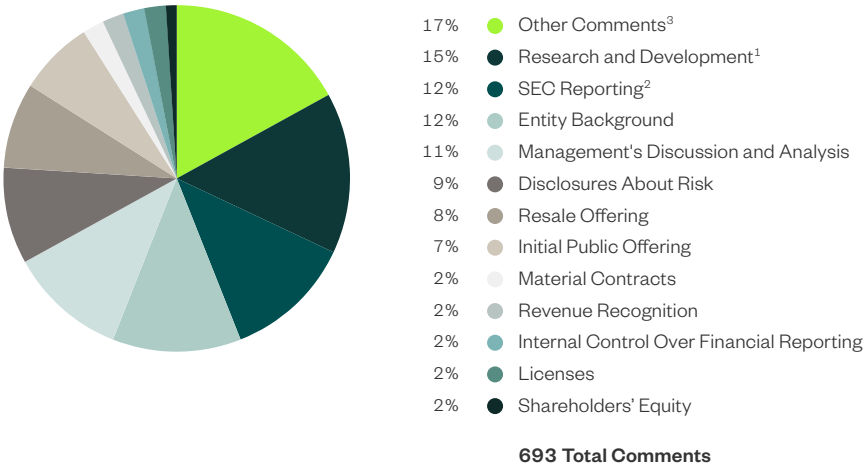
Comments were largely spread across key comment categories; those related to R&D were most prominent with a 15% share. Like the previous study, the SEC continued its focus on ensuring complete disclosure when it comes to companies' clinical trials and studies and requiring clarity and objectivity regarding developmental products and pipelines. A clear representation of R&D expenses also stemmed as a critical issue this period, with the SEC requiring many companies to disaggregate and report expenses by product candidate or program.

SEC reporting—or process compliance—was the next prominent category at 12%. Most comments, as in the 2021–2022 study, asked companies to make requisite and consistent disclosures throughout their prospectuses, including filing all material information.

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

Information around material contracts, revenue recognition, internal control over financial reporting, licensing agreements, and shareholders' equity constituted another significant block of SEC scrutiny, followed by various other comments targeting company-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 company-specific information.

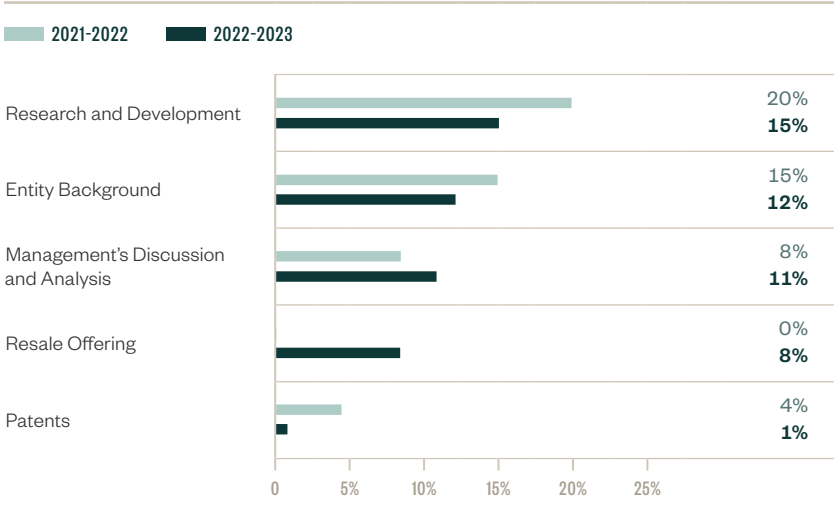
[2] Comments related to process compliance tend to be more administrative and formulaic, but because of the sheer volume of such comments, companies have an opportunity to significantly reduce filing delays by understanding the nature of scrutiny under this topic and taking the appropriate steps to comply.

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

SIGNIFICANT SHIFTS

Some topics saw a slight-to-significant shift in focus when compared to 2021–2022, 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, MD&A, resale offering, and patents.

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



Comments related to MD&A increased in focus by 3% while those related to resale offerings—not covered in the previous period's study—made up 7.8% of

the mix this time. Comments directed toward R&D decreased by 5.1%, while those related to entity background and patents slightly decreased by 2.9% and 2.7% respectively.

The mean variance of overall comments doubled from 1.3% in 2021–2022 to 2.6% this period, related to the sharp decline in total number of comments and shift in categorization spread.

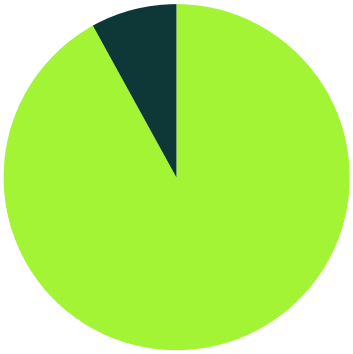
Requests for disclosures in new areas such as resale offerings emerged, while those related to typical and conventional topics were less prominent.

COMPOSITION BY FILING TYPE

While Form S-1 filings continued to lead in relation to SEC scrutiny like prior years, their share fell considerably from the last period. Of the total 693 comments analyzed in the study, roughly 70%—or 487 comments—were directed at Form S-1. This is a decrease from a share of 92% in 2021–2022.

The remaining 30% of comments were directed toward Forms 10-K, 10-Q, and 20-F filings.

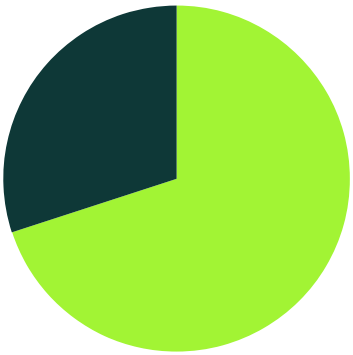
FIGURE 3: Percentage of Comments
By Filing Type



2021-2022

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

1,625 Total Comments



2022-2023

70% Form S-1 Filings
30% Forms 10-K, 10-Q, 20-F Filings

693 Total Comments

The nature of comment categorization varied among pre- and post-IPO companies as in prior years. Form S-1 comments related to R&D, process compliance, entity background, IPOs, and risk-based disclosures remained dominant.

Those related to pre-IPO applicants related to product pipeline, solution breakthroughs, potential market standing and anticipatory risks, and clarifying details of offering terms and price came into greater focus this period.

Comments related to resale registrations also came into focus this period and relevant Form S-1 filers were asked to provide more details on offerings, including what potential impact there could be on stock value.

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.

Comments centered on entity background and process compliance were more technical, such as requesting disclosure on a company's legal structure and material interests or having them file all necessary certifications.

Apart from new areas of focus that emerged this year, this trend was observed in the previous report as well.

NUMBER OF COMMENTS ISSUED

A key change in this period was the number of comments under review. Total SEC comments directed toward all four filings—Forms S-1, 10-K, 10-Q, and 20-F—halved by 57.4% from 2021–2022 to 2022–2023. This was contrary to the steadily increasing trend over the past two periods.

A core reason for this can be attributed to the IPO market, which went through an explosive boom until 2021 but has had a dramatic decline since. SEC comment letters on draft prospectuses for IPOs were the ones that contained the greatest number of comments, given they were directed toward applicants going public for the first time with sparse procedural compliance. Intuitively, if companies aren't filing for IPOs in the current dry spell and consequently not submitting their prospectuses, the potential for the SEC to issue comments will be lower.

Many comment letters this period were instead directed toward other filings, such as Forms S-3 and S-4, highlighting greater scrutiny on other filing types. In fact, public filers within the ambit of this study—Forms 10-K, 10-Q and 20-F—attracted a greater number of comments in absolute terms, in comparison to the previous study.

Trends in Form S-1 Filings

As expected, Form S-1 filings claimed more SEC attention than other filing types, making up 487 comments. That's 70% of the total 693 comments under review, considerably down from 2021–2022, when Form S-1 comments made up 92% of the mix.

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

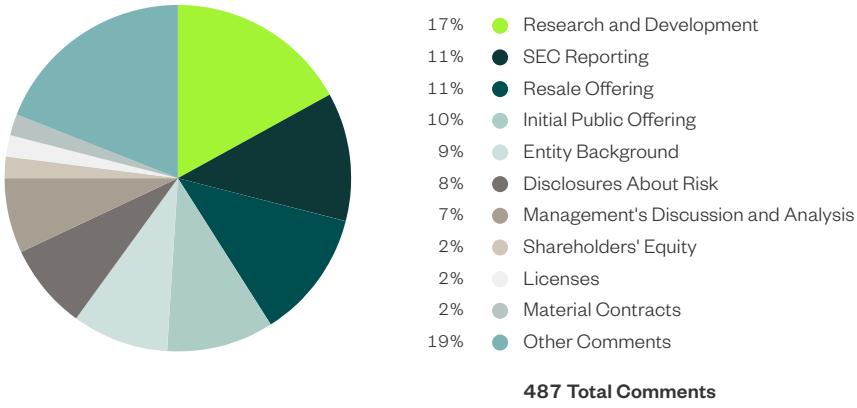
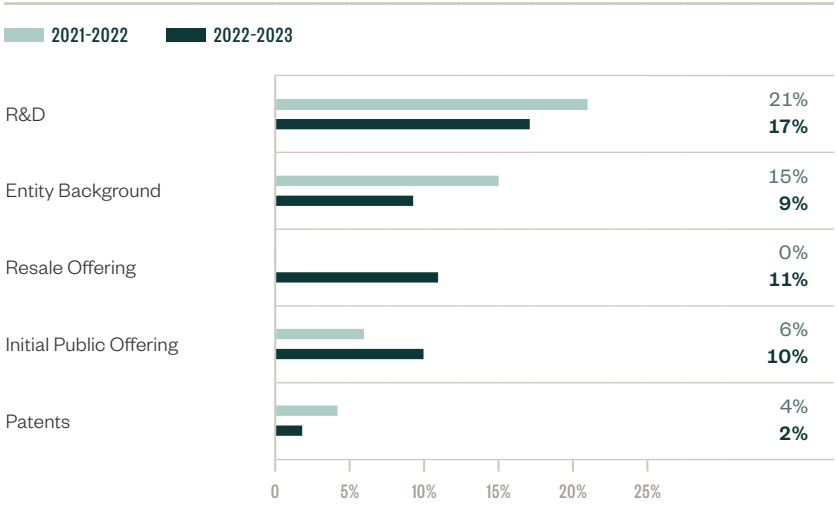


FIGURE 5: Significant Shifts in SEC Focus for Form S-1 Filings
By Ratio of Comments



In our comparative analysis, we noted categories that made slight to significant shifts relative to the 2021–2022 study. Comments related to IPOs increased by 4.1% while those related to resale offerings, which weren't covered in the previous period's study, made up 11.1%.

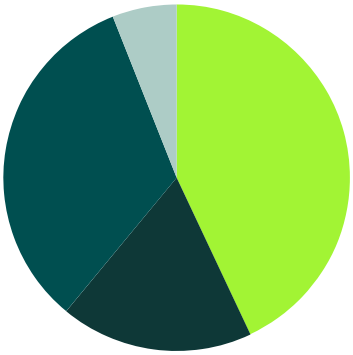
Focus on entity background and R&D dropped by 6.1% and 4.3% respectively, while focus on patents decreased by 2.3%.

The mean variance for Form S-1 comments more than doubled from 1.2% in 2021–2022 to 2.8% this period, highlighting much greater movement in the categorization spread.

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

R&D

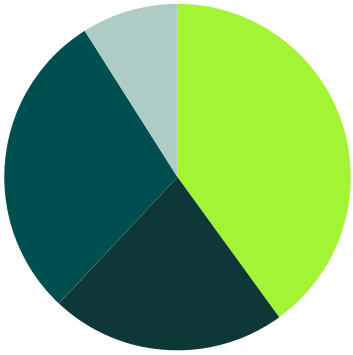
FIGURE 6: Number of Comments for Form S-1
By R&D-Related Subcategory



2021-2022

43%	Clinical Trials and Studies
18%	Product Pipeline
33%	Products and Services
6%	Other

314 Total Comments



2022-2023

40%	Clinical Trials and Studies
22%	Product Pipeline
29%	Products and Services
9%	Other

82 Total Comments

R&D is 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

Given the current scenario with subdued market confidence and unfavorable valuations, it's become imperative for companies to be objective with their R&D plans, keeping tabs on issues such as feasibility, marketability, and development timelines. All challenges from the initial scoping stage to the final commercialization need to be mapped, and financial requirements and ramifications need to be addressed.

Pipelines need to be realistic and not overly ambitious, while clinical trials should be objective enough to give a transparent picture.

Because these issues are critical, R&D prompted the greatest number of Form S-1 comments this period, making up 16.8% of the mix. While this decreased from a share of 21.1% in 2021–2022, the importance of this category in relation to all others remained.

In this category, comments directed toward clinical trials and studies stood out with a 40.2% share. Comments related to products in development and product pipelines followed, at shares of 29.3% and 22.0% respectively.

Other topics, though relatively low in number of comments, required greater disclosure on FDA filings and communications for developmental candidates as well as the costs undertaken to develop them.

CLINICAL TRIALS AND STUDIES

Like the previous period, the topic of clinical trials and studies stood out as the most prominent subcategory in R&D in 2022–2023, making up 33 comments, or approximately 40%.

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

This included details such as:

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

Companies were also asked to disclose the statistical significance of their clinical trials and explain how p-values are used.

The disclosure of all serious adverse events (SAEs) observed in all clinical trials remains critical. Companies must clearly disclose any SAE and the number of affected patients.

If a company believes there to be a potential for a registrational trial, it must disclose whether it has received any indication from the FDA for the same.

The SEC emphasizes the importance of balanced and objective disclosure of trial results using both quantitative and qualitative information. For example, all claims should be backed with concrete trial results presented in neat, tabular, and graphical representation, displaying all material trends to investors. When necessary, this should accompany comprehensive narrative disclosure that puts those results and graphs into context. Without this, the claims can be difficult to connect with the evidence provided.

Improper statements that imply that a clinical trial still underway is already successful should be avoided and companies must acknowledge obstacles that could hinder the applicability or validity of trial results. This can include jurisdictional restrictions or limitations from placing too much reliance on interim results.

However, it's not just organic clinical trials within a company that need attention. If a company is referencing external studies and trials to support its product development claims, proper descriptions and citations with reasonable comparisons are equally important.

Sample Comments

> *We note your disclosure that a clinical study of [drug name] confirmed its safety. Please indicate where this study was conducted, whether the study was powered for statistical significance and if the applicable regulatory authorities agreed with your conclusion. If true, please also indicate that other regulatory agencies may not agree with the study's safety conclusions and that you may need to conduct further studies in other jurisdictions.*

> *We note your disclosure that you believe your Phase 2 clinical trial for [candidate name], if successful, "has the potential to be registrational for [candidate name] in each of the three tumor types." Please disclose whether you have received any indication from the FDA that your Phase 2 clinical trial [will] be treated as registrational clinical trial such that a Phase 3 clinical trial will not be required.*

> *We note your disclosure that [candidate name] has been generally well-tolerated. However, it appears there are possibly treatment related serious adverse events (e.g., deaths) in your table on [page reference]. To the extent trial participants have experienced any serious adverse events, please describe the events and disclose the number of occurrences.*

> *You state that multiple large-scale studies have demonstrated that patients who fail to achieve their BP goal have a significantly elevated risk of developing heart disease, stroke, and kidney disease. Please revise your disclosure to cite the referenced studies, where appropriate.*

DEVELOPMENTAL PRODUCT PIPELINE

Given the nature of R&D, timing and execution of trials is critical, determining a candidate's progress and schedule toward commercialization. This developmental product pipeline information is material for investors and needs to be reported with informational graphics. Using tabular representation of the list of targets being researched, their intended indications, and their stage of development provides an overview of how large or small a company's research portfolio is and when it's expected to start generating revenue.

Consequently, this feature attracts a considerable amount of scrutiny every time and this period was no different. Comments related to product pipelines made up 22% of the R&D mix, registering a slight increase from last period's share of 17.8%.

The nature of disclosure required was like 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.
- Check that column widths depicting phases of clinical development are equal. This also includes columns related to preclinical development. A wider column may give an unfair representation of advancement.
- Place appropriate-length arrows next to each program to show its progress making sure the arrows don't encroach on phases not yet started. The arrows should give a fair representation of the current relational pipeline and not overstate the picture.
- Limit pipeline tables 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.
- Elaborate on those targets that are being developed jointly and clearly highlight which party oversees each development phase. For example, companies can add footnotes to their pipeline table to show which columns relate to work conducted by them and which relate to that by a third party.

Legibility also remains a fundamental component of pipeline tables. Registrants must make graphics clear and with legible text.

The key takeaway here is the need for concise and precise disclosure with diagrammatic representations giving a fair picture of timelines.

Sample Comments

> *Please revise your disclosure here and in your Business section to include a pipeline table depicting your clinical development programs, the specific indications being pursued, the phase or status of development for each product candidate including separate columns for preclinical development, Phase 1, Phase 2, and Phase 3 trials with arrows showing where each program has progressed, and a column indicating the timing of expected data from trials. If the pursuit of any of the indications may be delayed or are contingent on additional resources (such as marketing [drug name] as a malaria preventative treatment), please clearly note that in your table.*

> *Please revise to remove the "Discovery Programs" from the pipeline table. In this regard, we note that it appears premature to highlight them prominently in this table given their present development status. We further note that your Business discussion does not appear to provide disclosure concerning these programs.*

> *Please revise the table to include a column for Phase 3. Also, revise so that the "Preclinical" column is not wider than the Phase 1/2 column.*

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 that 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 29.3% of total R&D comments in 2022–2023, a slight decline from a share of 32.5% in 2021–2022.

Given the nature of this topic, the type of comments is company-specific year-over-year, and there isn't 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, the progress of their product candidates, what makes them unique, how they will eventually reach the market, and how they will be governed under the current regulatory scope.

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 or admitted in trials? • What is the duration of patient treatment? • How are preliminary or interim results turning out? Do they conflict with the targeted indication being planned? Can these results impact the possibility of approval for a certain indication?
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 Investigational New Drug (IND) applications submitted? If not, any rough idea of timelines? What is the expected pathway to approval? • 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? • Are approvals being sought in other countries? If so, what are the regulatory requirements there and how far have they been met/planned to be met? Will trial data in one jurisdiction bet admissible for approval in another?
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? • Is there or will there be a need for separate funding to advance development? Could this become a contingency to development? • Are there any concerns with regards to the cost or scalability of the manufacturing process?

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.

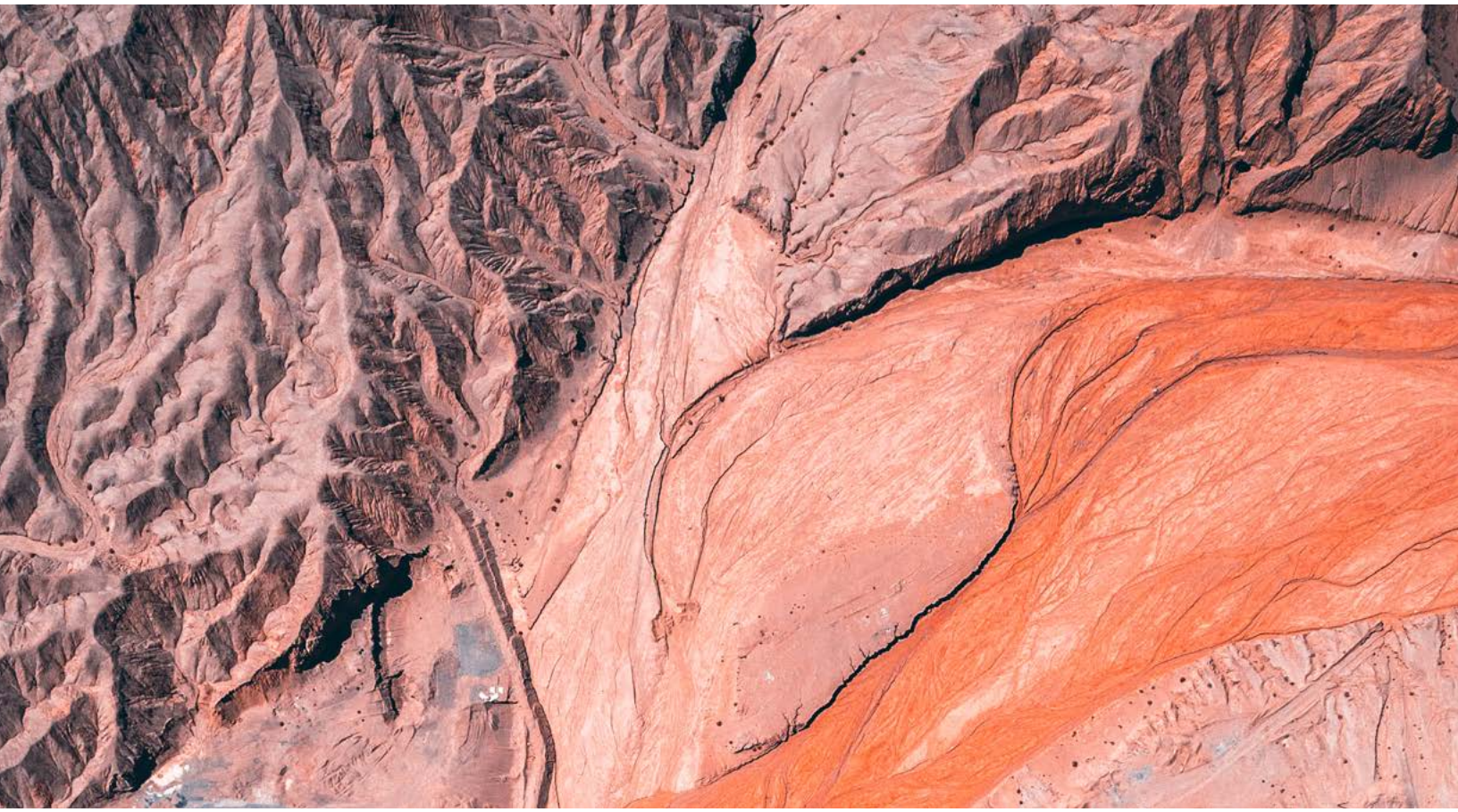
There's no procedural secret recipe for excelling in product-related disclosures. Making objective, comprehensive, and holistic disclosures can mitigate the scrutinizing comments.

Sample Comments

> *We note your statement on [page reference] and elsewhere that you plan to "rapidly" advance clinical development of [candidate name]. Please revise to remove such statements as they are speculative.*

> *Please expand your disclosure to include quantitative data supporting your claims that several in vivo and ex vivo experiments collectively support the potential efficacy of [candidate name] as a disease modifying therapy for patients with Netherton syndrome.*

> *We note your disclosure throughout your prospectus that you intend to market [candidate name] in the United States and the European Union, that you have an existing "CTA," and intend to submit a clinical trial application for your Phase 1b trial. Please briefly describe how the drug approval process works in the European Union, including the significance of a clinical trial application within this jurisdiction, the steps required to receive approval, and the steps you have taken to date to receive approval. Please also disclose in the related portion of the Business Section what "CTA" stands for, when you received approval for your existing CTA and when you intend to submit your clinical trial application.*



ENTITY-RELATED INFORMATION

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

2021-2022

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

222 Total Comments

2022-2023

16%	Market
30%	Products and Services
19%	Regulations
35%	Other

43 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 43 comments pertaining to entity-related information this period, making up 8.8% of total Form S-1 comments. This is down from a share of 14.9% in 2021–2022.

Despite the decline, the category remained a significant part of SEC examination, and included new areas of focus. For example, while comments related to current products and services continued to claim much of the attention, those related to regulations and legal structure saw a greater proportional share than in 2021–2022. This was followed by market-related comments, as in prior periods.

EXTERNAL ENVIRONMENT

Markets constantly evolve, and no business is immune to change. Issues such as recent macroeconomic disturbances, geopolitical tensions and a global economic slowdown created volatility, making it critical to monitor developments.

However, markets aren't 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.

Market-related comments made up 16.3% of entity-background comments this period, registering a slight increase from a share of 15.3% in 2021–2022.

The SEC highlighted this in this period's external environment questions, requiring registrants to provide the following:

- Basis for all market projections and market share claims, including material assumptions and uncertainty involved
- Explanation of addressable industry, the industry-specific conditions, and steps needed for commercialization, including any hurdles
- Narrative disclosure that reasons out larger market-related claims portrayed within infographics and charts
- Objective description of underlying competition and competitor profile

Sample Comments

> *With a view to disclosure, please explain to us the basis for your disclosure that the global sales opportunity is $250 million.*

> *Please discuss the competitive business conditions your [platform name] will face in the analytics industry. Please also disclose here your competitive position in the industry and any planned methods for competing.*

> *We note your revised disclosure in response to previous comment 1 and reissue the comment. Please disclose the material assumptions underlying the projections presented in this section. For example, please disclose any material assumptions regarding your projected market share and the annual cost of [treatment name].*

LEGAL STRUCTURE AND REGULATORY BACKDROP

Comments related to a company's legal or organizational structure and its regulatory scope made up 32.6% of the entity background mix, showcasing a substantial rise from a share of 13.5% in 2021–2022.

The SEC required companies to spell out all relevant regulations affecting their operations, as well as provide greater insights into what rules or guidelines they would be subject to in the future. This includes regulations related to the use and handling of hazardous materials and compliance with environmental norms.

Those fitting NASDAQ's definition of a "controlled company" were asked to provide appropriate disclosure in the prospectus cover page and summary, as well as give risk factor disclosure and expand on the corporate governance exemptions available to them.

Given the ongoing geopolitical tension between Russia and Ukraine, companies with material contractual arrangements across many other countries were asked to explain whether any import or export control restrictions and sanctions could impact their businesses and investors. A similar disclosure may now be required in response to the Israel-Hamas conflict.

In terms of legal structure, the SEC required registrants, especially those operating under complex network webs, to provide a diagram of their corporate structure and include a more complete narrative description of the various related entities and their roles. Registrants were also asked to specify how they will refer to these various entities within the registration statement so that there's no confusion to the reader about who and what is being referred to in different sections of the document. Ambiguous words such as we, us, and our should be avoided.

In a filing as comprehensive as a Form S-1, it's crucial to provide investors with a holistic understanding of how a company operates both in substance and form and its relationship with its other entities. This can impact policies and governance mechanisms such as how cash is transferred throughout the organization, how checks and balances are carried out, what management roles are as assigned, and other issues. This directly translates into control and ownership on a corporate level.

Sample Comments

> *We note your disclosure on [page reference]. Please advise whether you will be a controlled company under the Nasdaq rules upon the completion of your offering. If so, please include appropriate disclosure on the prospectus cover page and in the Prospectus Summary and provide risk factor disclosure of this status and disclose the corporate governance exemptions available to a controlled company. To the extent you will be a controlled company, the cover page and Prospectus Summary disclosure should include the identity of your controlling stockholder(s), the amount of voting power the controlling stockholder(s) will own following the completion of the offering and whether you intend to rely on any exemptions from the corporate governance requirements that are available to controlled companies.*

> *We note your disclosure that you have quality and contract manufacturing agreements relating to [product name] in place with [party name], among other entities, "to allow supply of [product name] to Australia, Europe, Canada/Israel/Latin America and Russia[.]" Please identify whether any import or export control restrictions and sanctions related to Russia's invasion of Ukraine are applicable to your business and describe the impact on the company and investors.*

> *We note your disclosure on [page reference] concerning the risks related to the use and handling of hazardous materials and compliance with environmental regulation. Please include a discussion of [the] material regulation applicable to your business and plans. Refer to Item 101(h)(4)(ix) and (xi) of Regulation S-K.*

> *Revise the summary to provide a diagram of your corporate structure and include a more complete narrative description of the various related entities and their roles.*

> *Please revise to clearly disclose how you will refer to the holding company, subsidiaries, and VIEs when providing the disclosure throughout the document so that it is clear to investors which entity the disclosure is referencing and which subsidiaries or entities are conducting the business operations. Refrain from using terms such as "we" or "our" when describing activities or functions of the VIE.*

PRODUCTS AND SERVICES

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

Comments regarding products and services portfolios constituted 30.2% of entity-background comments in 2022–2023, down considerably from a 56.3% share in 2021–2022. This area, however, continued to remain a dominant subcategory.

Like prior periods, the SEC required registrants to provide a balanced and holistic disclosure of their business offerings in the beginning of registration statements, given that this information provides context for all subsequent discussions in the document.

The Overview section of the prospectus is where registrants provide a clear picture of their entity-wide operations to date, including current offerings and revenue streams, if any, as well as how they're expanding their products portfolio 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.

Because it's a critical section, companies must present facts based on concrete data rather than including claims that could be misleading. As with R&D, companies must be cautious when presenting inferences about products based on the performance of others in the market, as these comparisons might not be based on comparable trial data.

Disclosure about dependence on third parties was emphasized this period, with the SEC requiring registrants to include the names of their principal suppliers or customers, 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. This disclosure is intended to provide investors with an objective depiction of entity operations and subjective statements and words such as best-in-class or first-in-class, must be avoided unless there's concrete and objective evidence to support the claim.

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

Any facts made about existing operations should also be cross-checked to ensure alignment with those published on a company's social media channels, websites, and other publicly accessible means.

As with the Products & Services topic in R&D, SEC scrutiny here remains largely company-specific and there isn't a template 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

Sample Comments

> *We note your disclosure on [page reference] that you intend to utilize intellectual property related to your cannabis brands. Please revise your Business section to disclose the intellectual property rights you have obtained and whether you intend to file for additional rights. Refer to Item 101(c)(1)(iii)(B) of Regulation S-K.*

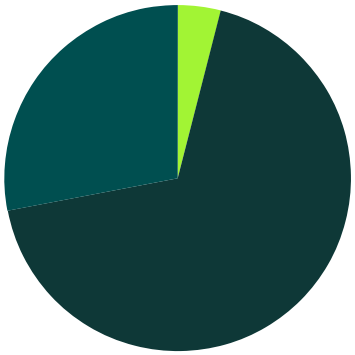
> *You state on [page reference] that you sell [product name] through your online store at [website name]. This website no longer appears to be active. We note previous visits to this webpage presented text stating the [online store name] is permanently closed. Please revise your disclosure or otherwise explain.*

> *Please revise the Business Overview section to highlight and clarify that to date you have not generated revenues from your [system name] and that you have not conducted clinical trials on any pharmaceutical drugs. Revise the penultimate paragraph in this section to clarify the scope of your operations to date to provide context to your disclosure that you are "preparing to ramp up" your business.*

> *We note your disclosure on [page reference] that you do not currently have any agreements with third-party manufacturers of your product candidates. Please also disclose whether you are dependent on any single or limited number of suppliers for your raw materials. If so, please expand your disclosure to discuss your sources, including the names of any principal suppliers. See Item 101(h)(4)(v) of Regulation S-K. To the extent you have experienced shortages of any raw materials, please expand your discussion to discuss the specific circumstances and the impact on your operations.*

RISK DISCLOSURES

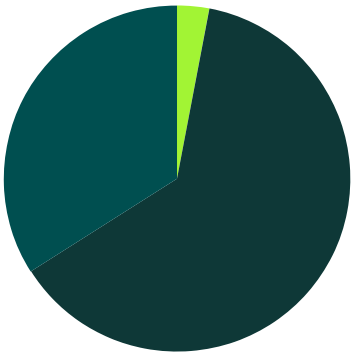
FIGURE 8: Number of Comments for Form S-1
By Risk Disclosures Subcategory



2021-2022

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

97 Total Comments



2022-2023

2%	Going Concern
63%	Risk Factors
34%	Updated Disclosures

41 Total Comments

Risk is an inherent part of the life sciences business ecosystem with each subindustry sector facing its own set of challenges and uncertainty. In the fast-paced life sciences industry, 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.

The exact degree of risk can vary based on subindustry sector-specific characteristics, as well as a company's own operational dynamics, such as its management structure, manufacturing capabilities, and compliance metrics. Unexpected events can create havoc in the sector.

Being able to anticipate, identify, measure, mitigate, and disclose these issues is a priority, especially for companies 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, 41 comments made up 8.4% of total Form S-1 comments, which is up from a share of 6.5% in 2020–2021.

Examples include risks driven by:

- **Product development.** Performance in clinical trials, clinical holds, safety concerns, data validity, FDA approval, and other areas.
- **Regulatory backdrop.** Can be related to product development or even operations at large, such as cross-border implications and working in countries with vulnerable or tight regulatory control.
- **Competition.** Possible potential substitutes, price wars.
- **Debt and valuation.** Chances of default, financial pressure, debt serving obligations, 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, outstanding rights, and structural volatility due to conflicting interests and roles.
- **Process orientation.** Internal and digital controls, weaknesses in internal control over financial reporting.
- **Material dependency.** Reliance on suppliers, customers, distributors, or other stakeholders.
- **Legal disruptions.** Due to geographical spread and control of operations.
- **Share price volatility.** Based on factors unrelated to company performance, market speculation.
- **Post-offering implications.** Negative pressure on the public trading price, in the event of large-scale resale offerings.
- **Going concern.** Recurring losses or dearth of capital resources affecting future operations, liquidity constraints.

Within these topics, comments focused on post-offering implications on public stock price this year, as there were many resale offerings filed by registrants.

The SEC continued to emphasize compliance with the amended Regulation S-K 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.

Meanwhile, some companies were asked to not only revise their risk factors for updates to account for any recent transactions and report the resulting new information.

Presentation and discussion are the key takeaways of this section. The identification of all material risks, as well as how they're presented and discussed in detail, are pivotal for managing SEC scrutiny.

Sample Comments

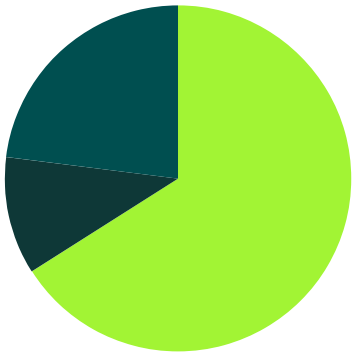
> *We note your last risk factor on [page reference] regarding the potential for generic competition for [product name] for malaria. Please tell us why including a summary of this risk factor in this section would not be appropriate or revise as applicable.*

> *We note that your summary risk factors are four pages in length. Please revise to limit to two pages and disclose only the principal factors that make an investment in the registrant or offering speculative or risky, as required by Item 105(b) of Regulation S-K.*

> *We note your disclosure on [page reference] that you do not currently own, lease, or operate a principal laboratory, R&D or manufacturing facility of your own and currently collaborate with various research institutions to perform R&D for your products, including [party name]. Please highlight this risk in your summary risk factors.*

MANAGEMENT'S DISCUSSION AND ANALYSIS

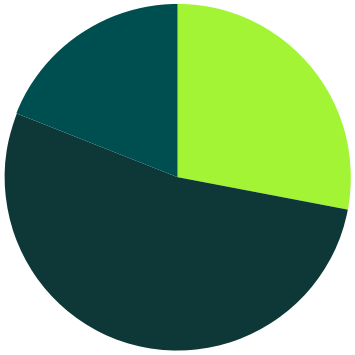
FIGURE 9: Number of Comments for Form S-1
By Management's Discussion and Analysis Subcategory



2021-2022

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

88 Total Comments



2022-2023

28% Critical Accounting Policies
53% Liquidity and Capital Resources
19% Results From Operations

36 Total Comments

MD&A 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
- Critical accounting policies
- Results from operations

Companies may also supplement this with disclosure of other information or parameters they believe are 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 numbers and signaling how they can change over time.

Regulation S-K Item 303 required disclosures "includes descriptions and amounts of matters that have had a material impact on reported operations, as well as matters that are reasonably likely based on management's assessment to have a material impact on future operations."

These basic parameters help companies present a transparent picture to investors about ongoing operations and frame discussions of their projections and expectations of the future.

The objective is to simplify disclosure requirements to eliminate repetitive or unnecessary disclosures, as well as allow companies to decide what information is specifically material to them and how best to disclose it.

Comments related to MD&A made up 7.4% of total Form S-1 comments in 2022–2023—a slight increase from a share of 5.9% in 2021–2022.

The nature of comments shifted slightly from prior periods, with a greater focus on liquidity and capital resources. The remaining comments focused on critical accounting policies and results from operations.

LIQUIDITY AND CAPITAL RESOURCES

Comments in this topic made up 52.8% of MD&A comments in 2022–2023, a jump from a share of 11.4% last period.

In line with Regulation S-K Item 303, the SEC asked registrants to discuss and analyze material cash requirements from known contractual and other obligations and specify obligation type and the relevant time period for related cash requirements. This included discussing any material change in cash and equivalents reported in financial statements.

However, the greatest increase in comments this period was attributable to registrants' offerings themselves, which had the SEC issuing comments of a similar nature across registration statements.

Where a company sees the likelihood of receiving limited proceeds in its offering from the exercise of stock warrants or stock options due to exercise and trading price disparity, it must expand its capital resources discussion to address any changes in its liquidity position, including the need to seek additional capital.

In addition to this, companies need to address going concern opinions issued by their auditors, if applicable, in their liquidity sections, as well as any other factors or new developments that can affect cash directly and indirectly. The impact of recent and ongoing business combinations is critical here.

Revenue projections must be duly explained and supported as they present possible changes to liquidity. This period, the SEC asked many companies that appeared to be missing their year-end revenue projections to provide updated information about their financial position and further risks to business operations and liquidity in light of these circumstances.

The message here is simple: Liquidity is one of the most important disclosures with relevant impact on investors' decision-making, and direct contractual obligations are just the tip of the iceberg. Registrants must take a comprehensive and expansive approach when addressing this section and include all factors pertaining to liquidity and capital resources.

Sample Comments

> *Considering the significant number of redemptions and the unlikelihood that the company will receive significant proceeds from exercises of the warrants because of the disparity between the exercise price of the warrants and the current trading price of the common stock, expand your discussion of capital resources to address any changes in the company's liquidity position since the business combination. If the company is likely to have to seek additional capital, discuss the effect of this offering on the company's ability to raise additional capital.*

> *Revise to expand your liquidity disclosures to include a discussion that analyzes material cash requirements from known contractual and other obligations, including specification of the type of obligation and the relevant time period for the related cash requirements, as required by Item 303(b)(1) of Regulation S-K. In that regard, we note you disclosed certain lease obligations as well as obligations under license agreements.*

> *Please revise your discussion of liquidity and capital resources to provide enhanced analysis and explanation of the sources and uses of cash and material changes in particular items underlying the major captions reported in your financial statements. Please assure that your discussion reconciles to the items and amounts presented on the face of your cash flow statements. Please also include a discussion of the conditions resulting in the going concern opinion included in the auditor's report, and, if relevant, address the fact that you are a holding company with no operations of your own and that you depend on your subsidiaries for cash.*

CRITICAL ACCOUNTING POLICIES

Comments directed toward critical accounting policies made up 27.8% of the MD&A mix in 2022–2023, which is substantially down from a share of 65.9% in 2021–2022. This was category has historically attracted most of the SEC's scrutiny in MD&A for years.

The nature of comments was largely the same, however. The SEC placed emphasis on registrants to outline their methods, assumptions, and estimates underlying critical accounting measurements and how changing them would impact financial results.

This included providing the accounting treatment for the following:

- Material collaborations and contractual arrangements
- Debt and equity instruments
- Share exchange transactions, like asset acquisitions and business combinations
- Treasury stock
- Arm's length basis for intercompany transactions
- Depreciation and amortization
- Net realizable value of inventory

For IPO registrants, as in prior periods, there were also comments pertaining to common stock value. Registrants 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.

This list is not exhaustive. The SEC can request filers present their critical accounting policies across relevant areas of business operations. Companies must design their accounting policies in accordance with authoritative guidance, implement them consistently, and discuss the nature of those accounting policies deemed as critical thoroughly in their public filings.

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 could suggest companies are successful in their efforts to continually make disclosure improvements in their filings, thus avoiding further scrutiny.

Sample Comments

> *We note your disclosure that [party name] acquired [other party name] via a 1:1 share exchange on [date]. Please tell us and disclose in your financial statements how you accounted for this share exchange transaction (e.g., asset acquisition, business*

> *combination, etc.). Please also describe the composition of any net assets acquired. To the extent that you determined that this share exchange was a business combination, provide the disclosures required by ASC 805-10-50.*

> *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. Please discuss with the staff how to submit your response.*

RESULTS FROM OPERATIONS

Comments related to operational results made up 19.4% of total MD&A comments this period, a slight decline from 22.7% in 2021–2022.

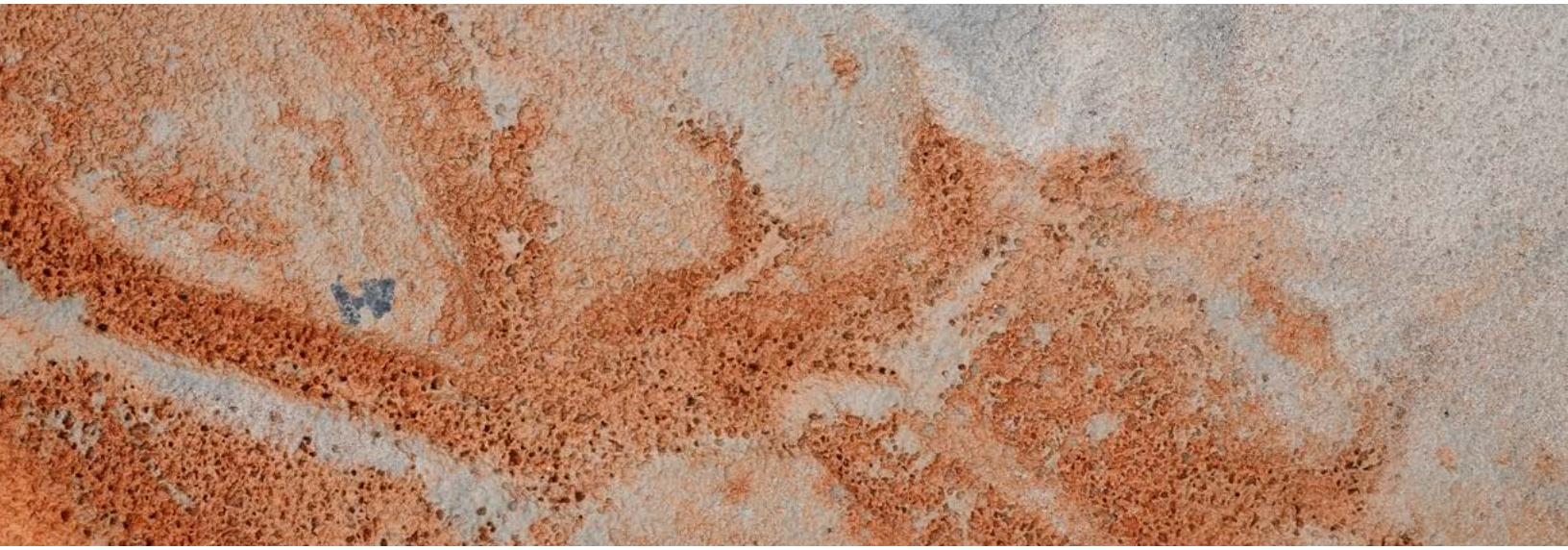
Like previous years, the SEC requested registrants to provide a more detailed analysis for each material quantitative change in operating measures from period to period, which included identifying and possibly quantifying all company-driven factors and market forces causing those changes. Some filers were also asked to update their business operations and financial position to account for the completion of any recent transactions and business combinations.

This subcategory's key takeaway is clear. Companies must present their operational performance in numbers and supplement this information with unambiguous and holistic narrative disclosure in a way that's transparent to investors.

Sample Comments

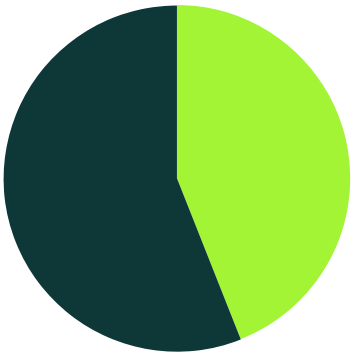
> *We note your disclosures that net losses increase due to the building of greenhouses and for planting the harvest. Please quantify the most significant reasons for the increase in labor and management expenses and general and administration expenses during the year ended December 31, [XXXY] compared to the year December 31, [XXXX].*

> *Please revise your discussion of your results of operations to quantify and describe the reasons for changes in each line item on your Statement of Operations, rather than just in total.*



IPO-RELATED DISCLOSURES

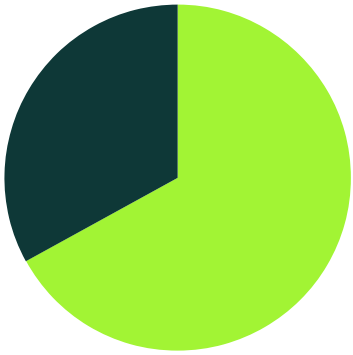
FIGURE 10: Number of Comments for Form S-1
By Initial Public Offering-Related Subcategory



2021-2022

44% Offering
56% Use of Proceeds

89 Total Comments



2022-2023

67% Offering
33% Use of Proceeds

49 Total Comments

Focus on IPO-related disclosures constituted 10.1% of total Form S-1 comments this period, registering an increase from a share of 6% in 2021–2022.

As in the past, these comments 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 Regulation S-K Items 501 and 504 as well as compliance with rules and regulations under the Securities Act of 1933 (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.

On a generic level, IPO applicants need to make sure they have the following disclosures duly provided:

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

First-time IPO filers who are new to the public filing process 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 actual offering made up 67.3% of IPO-related disclosures this period, which is up from a share of 43.8% in 2021–2022.

Like prior periods, most of these comments came from the Cover Page where the SEC required many registrants to clarify common features of their offering, such as the number and type of securities being registered, the price of securities, the termination date, and any arrangements to place the funds in an escrow, trust, or other account.

Concrete disclosure became even more critical during certain types of offerings. For example, in cases where the offering was being conducted at an assumed or assumed combined purchase price, the SEC requested companies to state the price of the securities to the public and clarify whether it will be fixed. If no price can be stated, then the filer must disclose the method by which the price will be determined.

Similarly, those registering multiple securities, such as shares and warrants, must clearly state the shares of common stock issuable upon the exercise of such warrants. This provides a comprehensive picture of all securities that are part of the registration statement's offering table.

If the offering is contingent upon securing listing approval in a market, then it must be stated clearly in the beginning of the statement.

Apart from the above common factors, using objective disclosure and language when discussing the type of offering being registered is crucial. The SEC issued several comments this period asking registrants to distinctly describe their firm commitment or best-efforts offerings and outline what they entail.

For example, for best-efforts offerings, the underwriter or placement agent isn't obligated to buy all the company's shares that are unsold in the IPO. Because of this, registrants undertaking such IPO can't be sure of the total amount of proceeds they'll receive and consequently shouldn't quote a number in their statements. Additionally, the language used to refer to the offering throughout the prospectus shouldn't erroneously sway between the characteristics of a firm commitment and best-efforts as it will only lead to greater confusion.

On a holistic level, clarity, consistency, and comprehensiveness remain crucial. IPO applicants should spend adequate time covering the required elements for the entire filing document including the Outside and Inside Cover Pages.

Sample Comments

> *Please revise your prospectus cover page to disclose the date on which the offering will terminate. For guidance, please refer to Item 501(b)(8)(iii) of Regulation S-K.*

> *Please disclose on your cover page whether your offering is contingent upon the final approval of your listing. Please ensure the disclosure is consistent with your underwriting agreement.*

> *We note your disclosure that your offering of common shares will be at an "assumed purchase price." Please revise to state the price of the securities to the public and clarify whether it will be fixed for the duration of the offering. If you are not able to state a price, explain the method by which the price is to be determined. Refer to Instruction 2 to Item 501(b)(3) of Regulation S-K for guidance. Also please revise to specify the date when this best-efforts offering will terminate. Refer to Item 501(b)(8) of Regulation S-K.*

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.

Consequently, the SEC's scrutiny of the use of proceeds, pursuant to Regulation S-K Item 504, maintains significant traction year-over-year. Comments pertaining to these disclosures made up 32.7% of the total IPO-related comments in 2022–2023, registering a considerable dip from a share of 56.2% in the previous report.

Like 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, providing clarity as to 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 offering's allocated proceeds 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 Regulation S-K Item 504 Instruction 4.

In cases where a fixed amount of proceeds to be raised can't be guaranteed, which is common in best-efforts offerings, registrants can provide a scenario analysis assuming different amounts of shares sold and state corresponding allocations for each.

Detail and precision remain the key takeaways. Companies must refrain from setting vague expectations and outcomes and instead provide a clear plan of action.

Sample Comments

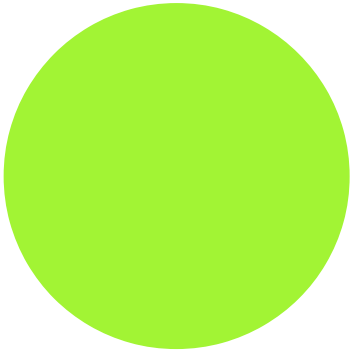
> *Please revise your Use of Proceeds section to show how the amount of proceeds will be allocated assuming different amounts of proceeds raised, and the number of shares sold, for example 100%, 75%, 50%, and 25% of the shares offered for sale in this offering.*

> *Please revise the disclosure in the first two bullet points to specify how much of the funding will be allocated toward each product candidate or program. Also disclose how far the proceeds will take you into the development process.*

> *We note your statement that you will require substantial additional capital in order to advance [candidate name] through clinical trials, regulatory approval and commercialization. In accordance with Item 504 of Regulation S-K, please revise your disclosure on [page reference] to clarify where the company intends to obtain such additional capital, as you have done on [page reference], or provide an appropriate cross-reference.*

RESALE OFFERING

FIGURE 11: Number of Comments for Form S-1
By Resale Offering Subcategory



Form S-1 offerings aren't only limited to IPOs. Companies can register stock for sale for various types of other transactions, including direct public offerings (DPOs), resale or selling shareholder offerings, private investment in public equity (PIPE), or equity offerings.

This period saw a sudden influx of comments pertaining to resale offerings, which, for the first time, made up 11.1% of Form S-1 comments. There were none such comments in the 2021-2022 period. This is a steep jump for one period.

The scrutiny was systematic, with the SEC issuing similar types of comments across companies and asking for the following:

- For each of the shares and warrants being registered for resale, disclose the price that the selling securityholders paid for such shares and warrants overlying such securities.
- Disclose the exercise prices of the warrants compared to the market price of the underlying securities, including out-of-the money implications.
- Outline differences in the current securities trading price and the price sponsors or private investors paid in order to highlight the fact that public security holders may not experience the same rate of return.
- Discuss the effect on market share price if the shares being registered for resale constitute a considerable percentage of the company's public float.
- Apart from these concerns, a slew of other comments followed suit, which, like those for IPOs, required filers to provide more clarity on the securities being offered and all offering terms.

Clarity, consistency and comprehensiveness are also essential for disclosures surrounding resale offerings. Companies need to provide complete disclosure on not just the offering itself, but also all its underlying implications, including its effect on share price, liquidity, and all other areas of operations.

With resale offerings making a rebound in the second half of 2023, adherence to the above will be critical to avoid unnecessary filing lags.

Sample Comments

> *For each of the shares and warrants being registered for resale, disclose the price that the selling securityholders paid for such shares and warrants overlying such securities.*

> *Please expand your discussion here to reflect the fact that this offering involves the potential sale of a substantial portion of shares for resale and discuss how such sales could impact the market price of the company's common stock.*

> *Highlight any differences in the current trading price, the prices that the Sponsor, private placement investors, PIPE investors and other selling securityholders acquired their shares and warrants, and the price that the public securityholders acquired their shares and warrants. Disclose that while the Sponsor, private placement investors, PIPE investors and other selling securityholders may experience a positive rate of return based on the current trading price, the public securityholders may not experience a similar rate of return on the securities they purchased due to differences in the purchase prices and the current trading price.*

SEC REPORTING

FIGURE 12: Number of Comments for Form S-1
By SEC Reporting Subcategory

2021-2022

19%	Discrepancies
24%	Filing of Exhibits and Other Material
36%	Updated Disclosures
21%	Other

155 Total Comments

2022-2023

11%	Discrepancies
34%	Filing of Exhibits and Other Material
46%	Updated Disclosures
9%	Other

56 Total Comments

No matter how well a company meets or exceeds its performance targets and discloses them in previous sections, it can't succeed without keeping proper and comprehensive compliance checks in place, regardless of how simple or complex the checks may be. Accordingly, SEC reporting, or process compliance, is a core topic that consistently makes up a sizable portion of SEC comments every year.

Meeting compliance requirements is a key parameter for every business in every industry, without which it would not be able to function and meet its objectives.

Whether expanding into new products and markets, building a proprietary platform, or exploring new financing routes, there will always be procedural formalities to meet and regulatory standards to adhere to.

In 2022–2023, comments related to process compliance made up roughly 11.5% of total Form S-1 comments, which is a slight increase from a share of 10.4% in 2021–2022.

Like prior periods, registrants were asked to add to or modify disclosures to align with Regulation S-K and Regulation S-X requirements to make their statements transparent, comprehensive, and unambiguous. This included providing all relevant exhibits, updating financial statements, adding the right number of signatures, or preventing discrepancies or conflicting statements throughout the document.

Even though comments in this section 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 modernizing drive and regulatory updates made in the last four years are meant to facilitate simple and comprehensive disclosures. Technological disruption and climate change have introduced additional issues critical to business reporting. The SEC is consequently designing new policies around these areas. An example is the recent proposal on climate disclosure rules.

Compliance reporting and monitoring is set to grow in the future. Comments here will remain important.

For this period, the sub-areas within this category with the most comments include those relating to correcting discrepancies, filing exhibits and other material, and updating disclosures.

DISCREPANCIES

In a document as large as a registration statement, the risk of conflicting disclosures between sections is high. Registrants are required to provide similar types of information in a variety of different contexts, which, if not carefully checked, can lead to inconsistent facts, figures, or opinions throughout the statement.

Consequently, this topic brings in a fair amount of SEC scrutiny every year and accounted for roughly 10.7% of process compliance comments in 2022–2023.

Like prior periods, companies were asked to correct numerical errors, clarify misleading product approval claims, ensure that subsidiary- and entity-related references correspond to those provided in the definitions page, and address apparent inconsistencies in resale-offering disclosures.

Companies were asked to make election of rights attached to the emerging growth company status consistent, as it should be clear if they decided to avail themselves of the extended transition period for complying with new or revised accounting standards.

Sample Comments

> *We note your financial statements are provided "in thousands" and so it appears your impairment loss you reference on [page reference] should be [correct figure]. Please revise or otherwise advise.*

> *Your disclosure here and on the cover page indicates that you have elected not to avail yourselves of the extended transition period for complying with new or revised accounting standards. Your risk factor disclosure on [page reference], discussion of the JOBS Act on [page reference], and Emerging Growth Company status on [page*

> *reference], however, indicates the opposite. Please revise to address this apparent inconsistency.*

> *You indicate on [page reference] and in your table on [page reference] that [product name] is being used off label for its radiation sensitizing properties. However, you indicate on [page reference] that it has been approved by the FDA as a radiation sensitizer. Please explain the discrepancy.*

FILING OF EXHIBITS AND OTHER MATERIAL

Given the wealth of information contained within registration statements, a thorough index of material exhibits and reference documents is necessary. Comments in this subcategory comprised close to 34% of the process compliance mix this period, marking an increase from a share of 24% last period.

Like the previous period, SEC scrutiny was standardized and procedural, requiring companies to comply with all exhibit guidelines as stipulated in Regulation S-K Item 601, which lists all documents that need to be filed with a 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.

Companies were asked to file all relevant documents as exhibits, and also file them in a searchable format, updated to reflect the latest versions. The SEC requires sound reasons for any documents not filed as required by Item 601.

Materiality is key word in deciding what to file and what to omit. Registrants should assess materiality by asking themselves these questions:

- Does this information provide insight into the company's objectives, structure, activities, and long-term plans?
- Does this information shed light on offering-related implications?
- Is this information often referred to in the main statement?

If the answer to any of the above is yes, they should consider including the information within the filing.

The SEC provides guidance for redacting sensitive company information. 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 not material and contains information treated as private or confidential. They must also include brackets indicating where the information is omitted from the exhibit's filed version.

Sample Comments

> *We note your disclosure that [party name] entered into an agreement and plan of merger with [other party name]. Please file the merger agreement as an exhibit or tell us why such agreement is not required to be filed. See Item 601(b)(2) and (10) of Regulation S-K.*

> *We note your disclosure in the footnotes to the exhibit index that certain portions of Exhibit [name] have been redacted. If you intend to redact information pursuant to Item 601(b)(10)(iv) of Regulation S-K, please revise to include a prominent statement on the first page of such redacted exhibit that certain identified information has been excluded because it is both not material and the type of information that the registrant treats as private or confidential. Refer to Item 601(b)(10)(iv) of Regulation S-K.*

> *Please refile your exhibits in the proper text-searchable format. Please refer to Item 301 of Regulation S-T. Please also revise to provide the information required by Item 16(a) of Form S-1.*

UPDATED DISCLOSURES

Like the previous report, a considerable number of process compliance comments were directed at updated disclosures, a category which requires registrants to update information throughout the prospectus and clarify certain areas.

Comments in this area made up 46.4% of process compliance comments this period, registering an increase from a share of 35.5% in 2021–2022.

Registrants were asked to undertake the following:

- Update financial statements
- Provide recent audit reports
- Disclose the tenure of principal accountants
- Update statements in the document related to events that already occurred including completed business combinations, resale of shares, and manufacturing activities
- Revise incorrect references to legal provisions and safe harbor
- Clarify on incorporation by reference
- Ensure the validity of cross-references throughout the document
- Update and correct capitalization tables
- Provide greater disclosure in the Principal Stockholders' table

Exclusive forum provisions remained a key area of focus. Companies were asked to clarify whether the provision applies to actions arising under the Securities Act or the Securities Exchange Act of 1934 (Exchange Act) and state this clearly in the prospectus. It's vital to provide the scope of this action and its enforceability on potential claims.

Because this section deals with information provided throughout the statement, SEC scrutiny is expected to continue. The most important consideration for registrants is keeping information as clear and up-to-date as possible to prevent recurring revisions.

Sample Comments

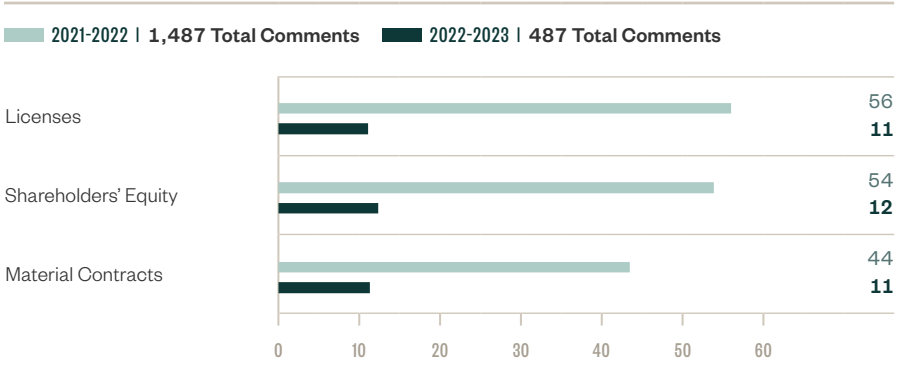
> *Please revise to update your disclosures throughout the filing to reflect the completion of the business combination and related redemptions. For example, on [page reference] you reference potential changes in [company name's] future reported financial position and results based on an estimated increase in cash based on either the maximum redemption scenario or no shareholder redemptions. Because the redemptions have now occurred, this disclosure should be revised to reflect the [percent] redemption rate and the actual impact on liquidity and capital resources as of the date of the prospectus.*

> *We note your disclosure here that the courts of the [location] and appellate courts therefrom shall be the sole and exclusive forum for certain proceedings. Please revise this section to disclose how this provision will be applied to claims brought under the Securities Act and the Exchange Act; address any uncertainty about enforceability; and, to the extent that the provision applies to claims under the federal securities laws, include risk factor disclosure.*

> *Please revise here and throughout to update your disclosures throughout the filing and address areas that appear to need updating or that present inconsistencies. Non-exclusive examples of areas where disclosure should be updated are as follows:*
>
> - *Disclose whether the Business Combination has been completed. To the extent the Business Combination has been consummated, please tell us why it is material to investors to present a discussion of the mechanics of the Business Combination in the Prospectus Summary.*
> - *Your disclosure on [page reference] indicates that the results of one of your clinical studies are "expected to be available by [date]."*
> - *Your disclosure on [page reference] indicates that you expect to pay an annual basis to*
> - *Be certain of your named executive officers in the first quarter of calendar year [XXXX].*
> - *Your Principal Stockholders table should show beneficial ownership following the Business Combination.*

OTHER DISCLOSURE TOPICS

FIGURE 13: 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 2022–2023, including comments related to the following:

- Shareholders' equity
- Licensing agreements
- Material contracts

Together, these comprised roughly 7% of total Form S-1 comments.

SHAREHOLDERS' EQUITY

The capital structure of a company: the nature and composition of shareholders' equity, informs the investor of interest and control dynamics. This area is typically of intense investor focus. Consequently, the need to make unambiguous disclosures here is unparalleled.

Comments related to shareholders' equity made up 2.5% of total Form S-1 comments this period, registering a decline from a share of 3.6% in 2021–2022.

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

- Beneficial ownership percentages
- Indirect control
- Rights governing each class of shares
- Valuation changes
- Impact of dividends

- Effects of dilution

The SEC emphasized investment-related disclosures this period. Several 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

> *We note your principal stockholders table is missing footnotes that appear in the table. Please revise or otherwise advise.*

> *We note on [page reference] that you will affect a stock split on xx, [date]. If the stock split will occur prior to effectiveness of the registration statement, please revise your historical financial statements to reflect the stock split based upon the guidance in ASC 260-10-55-12 and SAB Topic 4(C). This also applies to your capitalization table on [page reference]. Please also note the need for your independent auditor to reference and dual-date their audit opinion for the aforementioned stock split.*

> *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 your company 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.*

LICENSING

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

Comments directed at licensing agreements constituted 2.3% of total Form S-1 comments this period, which is a slight decline from a share of 3.8% in 2021–2022.

The nature of comments remained consistent as in prior periods. 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 or circumstances that can lead to agreement restrictions, return of unearned revenue
- Termination provisions

To the extent material, some registrants were also required to file the licensing 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

> *We note your disclosure here that you may be obligated to pay a tiered percentage royalty on annual net sales ranging from a low single-digit up to low double-digits. The upper bound of the range is very broad and therefore does not provide investors with a meaningful understanding of the potential royalty payments. Accordingly, please revise so that the range of the royalty rate does not exceed 10 percentage points.*

> *Please revise to indicate which of your product candidates and programs are subject to the license agreement.*

> *Please revise the discussion of your licensing agreements to disclose the duration of the agreements, any termination provisions, the aggregate amounts paid to date and the aggregate future potential milestone payments payable. Please also file these three agreements as exhibits to the registration statement. Refer to Item 601 of Regulation S-K for guidance.*

MATERIAL CONTRACTS

A company's material contracts may include key agreements that outline its strategic collaborations, alliances, and significant partners for fundamental operations and future growth and expansion. Companies aren't just coming together to capitalize upon each other's expertise or for competitive advantages, but rather to become partners in large-scale ventures that forward business expansion.

The nature, scope, and size of these collaboration agreements can take all shapes and forms and reside in every area of the value chain. Agreements can range from product development alliances to exclusive licensing agreements, dominant supplier and distribution relations, funding grants, and more.

Firms might have operational dependency on the 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 and consequently attracts a fair degree of SEC scrutiny every year. Comments related to material contracts made up 2.3% of total Form S-1 comments this period, which is largely in line with 2021–2022.

The nature of comments was similar, with the SEC asking registrants to undertake certain steps to:

- Disclose all material provisions of agreements. This includes the following:
  - Identification of all parties involved
  - Each party's rights and obligations
  - Nature of intellectual property or other tangible and intangible assets covered
  - Milestone payments
  - Royalty range or term
  - Termination provisions
  - Agreement contingencies
- Discuss the implications of these agreements on business operations, both positive and negative, especially outlining the risks they present, if any, to other stakeholders.
- File the agreements as exhibits pursuant to Item 601(b)(10) of Regulation S-K.
- Determine the materiality of a contract is a matter of judgment, and a standardized rule would help companies avoid under-reporting. Any agreement that affects or can significantly affect metrics such as revenue, cost, intellectual property, or developmental pipelines should be described as material.

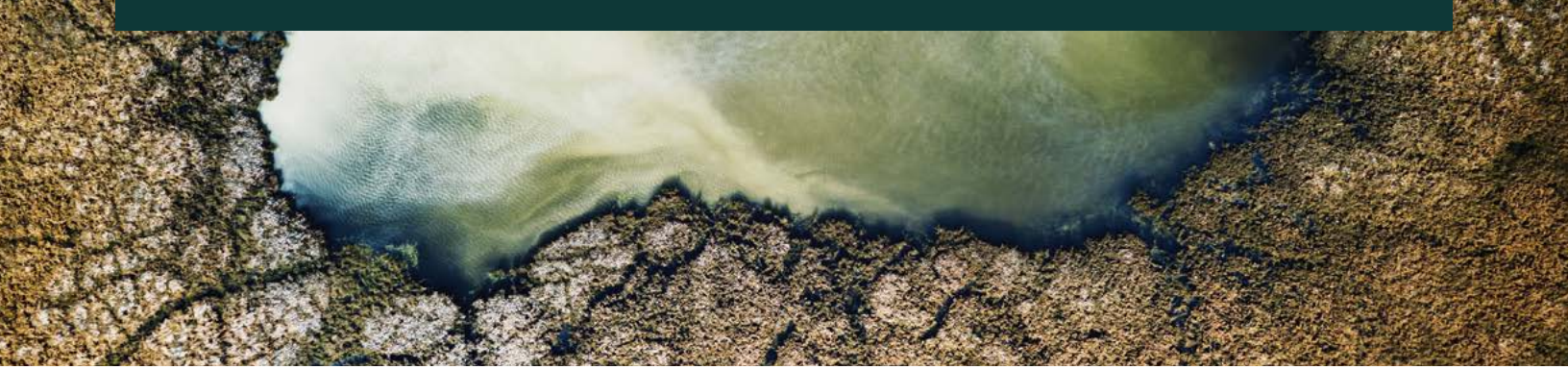
The SEC's modernization amendments have reduced the burden of reporting certain information that may be competitively sensitive; however, they don't remove the onus on filers to disclose all information that's material to investors.

Sample Comments

> *We note your disclosure that you receive a majority of your revenues from sales of the [product name] product to the [party name] and that you have an existing contract with the [party name]. Please revise your disclosure here to note the termination date of this existing contract.*

> *We note the agreements you intend to file as Exhibits. Please describe the material terms of each such agreement, including each party's rights and obligations thereunder, the duration of each agreement and any royalty and termination provisions, or tell us why such disclosure would not be appropriate. We also note you have rights to use patents, manufacturing information and non-clinical and clinical data licensed from the [party name] for [drug name] for all indications except P. vivax malaria. Please file that agreement as an exhibit, and, in an appropriate location, disclose how your licensing arrangement, which you disclose excludes P. vivax malaria, would impact any targeted marketing efforts of [product name] for its currently approved use.*

> *You disclose here that you accounted for the [agreement name] as an asset acquisition of IPR&D assets with no alternative future use. Please address the following comments:*
>
> - *Please revise to provide more details for the components acquired under the [agreement name]. In that regard, we note you disclosed elsewhere that you acquired three families of patent filings related to [candidate name] under "Patents" at [page reference] and acquired sufficient [candidate name] drug substance and drug product from [party name] to treat several hundred patients under "Manufacturing" at [page reference].*
> - *Please tell us in your response the accounting literature you relied upon to determine the asset acquisition accounting.*



SECTION THREE

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 30% of the total 693 comments analyzed in 2022–2023, which is a large increase from a share of 8% in 2021–2022.

Topics such as MD&A, entity background, process compliance, and R&D were prime focus areas and made up 127 of the total 206 comments.

This was followed by comments related to risk-based disclosures and internal control over financial reporting, as well as those pertaining to the adoption of the revenue recognition policy.

Unlike its Form S-1 scrutiny, the SEC focused on companies' operational activities, financial and operating results, and internal controls, along with requiring consistent disclosures across filings. While emphasis on R&D grew significantly, the scrutiny centered on expense-related disclosures as opposed to pipelines and product development.

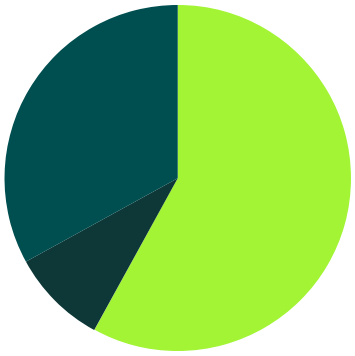
FIGURE 14: SEC Comment Categories for Forms 10-K, 10-Q, and 20-F Filings

2022-2023

19%	Management's Discussion and Analysis
18%	Entity Background
13%	SEC Reporting
11%	Research and Development
9%	Disclosures About Risk
6%	Internal Control Over Financial Reporting
5%	Revenue Recognition
18%	Other Comments

206 Total Comments

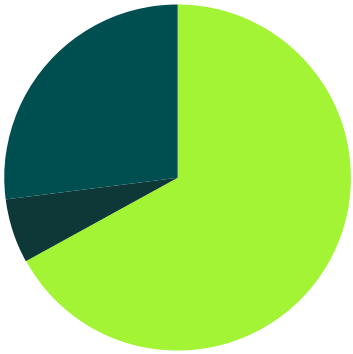
FIGURE 15: Breakdown of Forms 10-K, 10-Q and 20F Comments
By Filing Type



2021-2022

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

138 Total Comments



2022-2023

67% Form 10-K
6% Form 10-Q
27% Form 20-F

206 Total Comments

Form 10-K submissions attracted the greatest SEC scrutiny among all the three filings in 2022–2023, constituting 67% of the total 206 comments. Form 20-F filings earned 27% of the mix and Form 10-Q filings earned the remaining 6%.

This distribution has been changing over the years. The skew in SEC comments toward Form 10-Ks has been easing while attention to Form 20-Fs has been increasing steadily.

Fewer comments on a form can imply better compliance. However, with Form 20-Fs earning more comments, it's possible that the SEC is placing greater scrutiny on such filings and foreign private issuers need to pay greater attention to disclosures and matters of compliance.

FIGURE 16: Key Areas of SEC Focus for Forms 10-K, 10-Q, and 20-F Filings
By Number of Comments

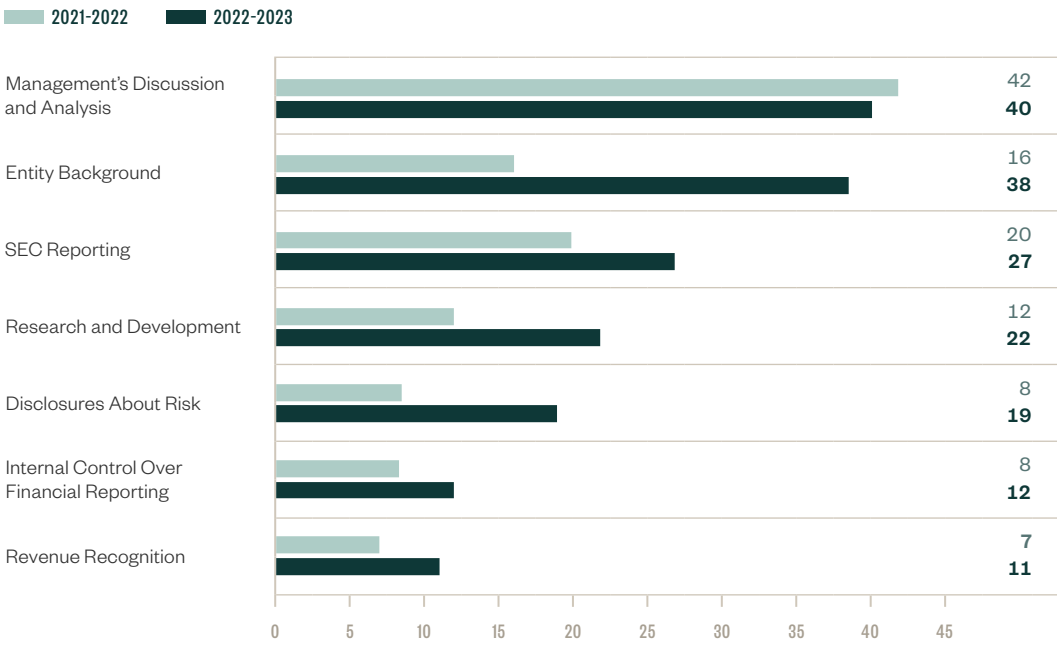
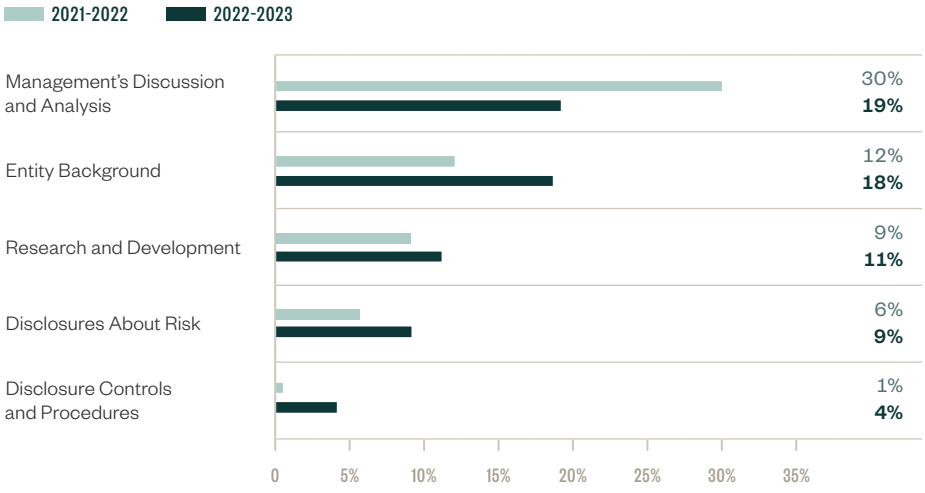


FIGURE 17: Significant Shifts in SEC Focus for Forms 10-K, 10-Q, and 20-F Filings
By Ratio of Comments



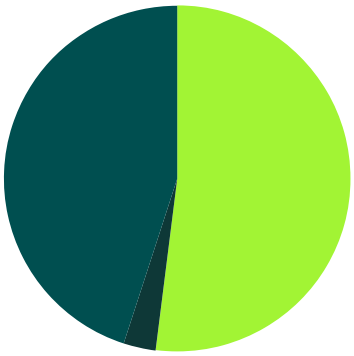
SEC scrutiny around entity background, risk-based disclosures and disclosures on controls and procedures, by ratio of comments, grew by 6.8%, 3.4%, and 3% respectively, from 2021–2022 to 2022–2023. Comments related to R&D grew slowly, increasing by 2% on a relative basis.

On the other hand, focus on MD&A dropped drastically by 11%.

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 MD&A 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 18: Number of Comments for Forms 10-K, 10-Q, and 20-F Filings
By Management's Discussion and Analysis Subcategory



2021-2022

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

42 Total Comments

2022-2023

58%	Critical Accounting Policies
0%	Liquidity and Capital Resources
42%	Results From Operations

40 Total Comments

Although the MD&A section had the greatest decline by ratio of comments, it still made up the largest absolute number of comments this period, constituting 19.4% of the Forms 10-K, 10-Q and 20-F mix.

Pre-IPO candidates going public for the first time and publicly listed companies making recurrent filings must both provide sound disclosures on operational results and business outlook. Company performance is highly dynamic and its derivation and presentation in financial statements is subject to accounting amendments or revisions every year. These factors need to be reported with a comprehensive narrative and discussion that provides complete transparency to investors on the company's past, present and future.

The recent amendments to Regulation S-K Item 303 have helped streamline such disclosures and provided filers with more flexibility on 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.

MD&A comments, like the last period, were largely focused on critical accounting estimates and results from operations.

Companies were requested to outline their accounting methodology for all core operational parameters, citing the authoritative literature on which they relied.

Such parameters included:

- Consistent accounting in multiparty agreements and alliances, including licensing, asset or share purchase agreements, and other products and services designed with third parties
- Policy on R&D expenses
- Treatment of intangibles
- Revenue recognition including determination of transaction price and description of performance obligations
- Measurement of deferred tax liabilities and deferred tax assets
- Any changes to estimations such as contra revenue accounts
- Determination of fair value including equity awards and other assets, especially in purchase agreements
- Deconsolidation
- Use of non-generally accepted accounting principles(GAAP) financial measures, including compliance with Item 10(e) of Regulation S-K and the Compliance and Disclosure Interpretations on Non-GAAP Financial Measures.

Prioritizing analysis over narration was an important factor. The SEC told several filers their disclosures of critical accounting estimates were merely a description of how they were accounting for items in accordance with the United States generally accepted accounting principles (GAAP). However, what's really needed is to provide investors with a complete understanding of how the critical estimates are derived, and how the uncertainty associated with those estimates may impact their consolidated financial statements.

A similar detailed reasoning was required for disclosures on operational results. The SEC required companies to engage in a detailed discussion for any material changes in operational results and present a quantified analysis of significant factors that led to changes.

External drivers can include:

- Supply chain disruptions
- Inflation
- Generic competition
- Macroeconomic instability

Internal fluctuations can include:

- Impact of acquisitions
- Weakening of customer credit
- Manufacturing defects

The key here is identification, quantification, and discussion. Companies must communicate fluctuations in core metrics like revenue, cost, and expenses in a way that investors can understand the magnitude and relative impact of each factor. Narrowing down such an analysis at a segment level, or even a business unit level, may be necessary at times when such causal relationships get too complex.

The intent behind the simplification and modernization of Item 303 of Regulation S-K is for filers to clearly and transparently communicate in a manner that best represents the firm.

Sample Comments

> *Please disclose your accounting policies for R&D expenses and intellectual property intangible assets. With reference to the nature of the intellectual property acquired as disclosed on [page reference], please address how you determined there is an alternative future use for these assets, such that it was appropriate to capitalize the cost of these assets. Refer to ASC 730-10-25-2(c).*

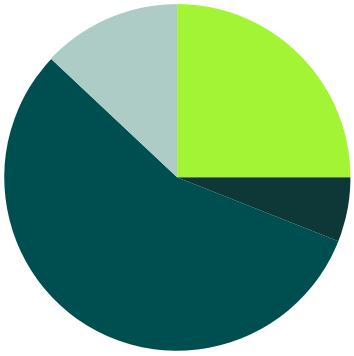
> *It appears from your disclosure that 100% of your sales for the three months ended [date] were returned. Please revise to disclose the reason for the significant returns and how these are reflected in your financial statements. In addition, clarify why revenue was recognized for these sales and how these returns impact your revenue recognition policy. Your revenue recognition accounting policy should be revised to address returns.*

> *Please quantify each of the factors you noted for the selling, general and administrative expenses line item that explains the increase and/or decrease from the current period to the respective prior period, as applicable. For example, you disclosed that selling, general and administrative expenses for your [segment name] increased as compared to the prior fiscal year and were primarily attributed to higher headcount, professional fees and stock-based compensation expense as compared to the same period of the prior year. Please quantify each of the factors noted.*

> *Please revise future filings to provide a more comprehensive and quantified discussion and analysis of your results of operations, including the factors that impacted your results between comparative periods. You should also discuss how much of the increase in revenues was from acquisitions or changes in volume, selling prices or product mix. Refer to the requirements of Item 303(b)(2) of Regulation S-K.*

ENTITY-RELATED INFORMATION

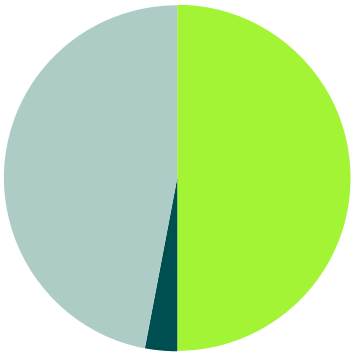
FIGURE 19: Number of Comments for Forms 10-K, 10-Q, and 20-F Filings
By Entity Related Subcategory



2021-2022

25%	Legal Structure
6%	Other
56%	Products and Services
13%	Regulations

16 Total Comments



2022-2023

50%	Legal Structure
0%	Other
3%	Products and Services
47%	Regulations

38 Total Comments

The SEC's focus on entity background has increased significantly for public filers over the last two periods. In 2021–2022, comments directed toward entity-related

disclosures grew from zero to 11.6% of the Form 10-K, 10-Q, and 20-F mix. This period, these comments have further increased their share to 18.4%.

Examinations were largely focused on companies' legal structures including subsidiaries as well as the prevailing regulatory scope. A systematic set of comments were targeted at companies having operations in foreign jurisdictions with a complex network of subsidiaries. This included scrutiny of China-based companies.

Over the last several years, the Division of Corporation Finance has issued specific guidance on disclosure obligations of companies based in or with a majority of operations in the People's Republic of China. This covers a wide range of disclosure issues, including those related to the variable interest entity structure, the reliability of financial reporting, the regulatory environment in China, and corporate governance matters. Consequently, the SEC has issued a sample letter to companies regarding China-specific disclosures, which sets out requirements in the following three areas.

HFCAA Disclosures

Public companies identified as Commission-Identified Issuers (CIIs) under the Holding Foreign Companies Accountable Act (HFCAA) must comply with the submission and disclosure requirements under the HFCAA and commission rules for each year in which they are identified as CIIs on the SEC's website.

For CIIs that are non-US issuers, the SEC has set out a specified set of disclosures related to matters that indicate control by the government of the People's Republic of China (PRC) or the Chinese Communist Party (CCP). The sample letter provides guidance as to likely requests or disclosure mandates the SEC staff will make.

Material Risks Disclosures From China-based Operations

The SEC seeks disclosures about any material impacts that intervention or control by the PRC in the operations of these companies has or may have on their business or the value of their securities.

Such control can be established in ways that go beyond appointing members to the board or having formal powers under the company's organizational documents. Under the Securities Act and the Exchange Act, control "means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise."

Impact of Specific Statutes

Companies may be required to make disclosures related to material impacts of certain statutes. This includes ones like the Uyghur Forced Labors Prevention Act (UFLPA) which, on December 23, 2021, became law in the United States. The UFLPA prohibits the import of goods from the Xinjiang Uyghur Autonomous Region of the PRC. Firms with operations in, or relying on counterparties conducting operations in, the Xinjiang Uyghur Autonomous Region would need to evaluate and discuss the implications of UFLPA on their businesses.

The SEC encourages companies to check its illustrative letters for guidance on sample comments that can be issued from time to time. These sample comments aren't exhaustive, and companies should watch for additional developments and issues, especially those pertaining to their industry, and contact the industry office that's responsible for the review of their filings with any further questions.

Filers should also be aware that the Public Company Accounting Oversight Board's (PCAOB) successful 2022 inspection of China- and Hong Kong-based audit firms

doesn't permanently rule out the delisting risk for China-based registrants under the HFCAA. The PCAOB determines every year whether it can fully inspect and investigate audit firms in China and Hong Kong, and any gaps can raise this risk.

As geopolitical vulnerabilities increase, companies with a foreign footprint must account for risks and uncertainties across their complete line of operations. A clear organizational snapshot should be provided to investors in companies' filings, coupled with the ramifications of each location. Any ambiguity in the same can attract SEC comments.

Sample Comments

> *Please prominently disclose whether your auditor is subject to the determinations announced by the PCAOB on December 16, 2021 and whether and how the Holding Foreign Companies Accountable Act ("HFCAA") and related regulations will affect your company. Additionally, please disclose prominently that you have been included on the Commission's conclusive list of issuers identified under the HFCAA as having retained a registered public accounting firm to issue an audit report where the firm has a branch or office that: (1) is located in a foreign jurisdiction and (2) the PCAOB has determined that it is unable to inspect or investigate completely because of a position taken by an authority in the foreign jurisdiction.*

> *Clearly disclose how you will refer to the holding company and subsidiaries when providing the disclosure throughout the document so that it is clear to investors which entity the disclosure is referencing and which subsidiaries or entities are conducting the business operations. For example, disclose, if true, that your subsidiaries conduct operations in China.*

> *At the onset of Item 4, please disclose prominently that you are not a Chinese operating company but a Cayman Islands holding company with operations conducted by your subsidiaries and through contractual arrangements with variable interest entities (VIEs) based in China and that this structure involves unique risks to investors. If true, disclose that these contracts have not been tested in court. Explain whether the VIE structure is used to provide investors with exposure to foreign investment in China-based companies where Chinese law prohibits direct foreign investment in the operating companies and disclose that investors may never hold equity interests in the Chinese operating company. Your disclosure should acknowledge that Chinese regulatory authorities could disallow this structure, which would likely result in a material change in your operations and/or a material change in the value of your securities, including that it could cause the value of your 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.*

> *Disclose each permission or approval that you or your subsidiaries are required to obtain from Chinese authorities to operate your business and to offer securities to foreign investors. State whether you or your subsidiaries are covered by permissions requirements from the China Securities Regulatory Commission (CSRC), Cyberspace Administration of China (CAC) or any other governmental agency that is required to approve your operations, and state affirmatively whether you have received all requisite permissions or approvals and whether any permissions or approvals have been denied. Please also describe the consequences to you and your investors if you or your subsidiaries: (i) do not receive or maintain such permissions or approvals, (ii) inadvertently conclude that such permissions or approvals are not required, or (iii) applicable laws, regulations, or interpretations change and you are required to obtain such permissions or approvals in the future.*

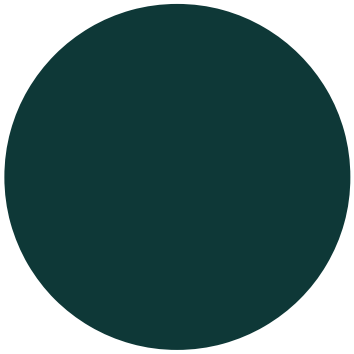
R&D

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

2021-2022

8%	Clinical Trials and Studies
75%	Expenses
8%	FDA Filings and Communications
8%	Products and Services

12 Total Comments



2022-2023

0%	Clinical Trials and Studies
100%	Expenses
0%	FDA Filings and Communications
0%	Products and Services

22 Total Comments

The SEC's scrutiny on R&D for public filers made up 10.7% of total Forms 10-K, 10-Q, and 20-F comments, registering an increase from an 8.7% share last period.

Expenses were the focal point this period. Given that R&D is the fulcrum of the life sciences business model, it's an area that must be duly tracked, recorded, monitored, and reported.

Consequently, nearly all the SEC's comments asked companies to be more proactive with disclosing their R&D expenses, given that many had claimed this to be a central expense item or that it had increased drastically over the years. Filers were asked to provide more details about their R&D expenses for each period presented in results of operations per Item 303 of Regulation S-K, which includes but is not limited to quantification by product or program, as well as by the nature of the expenses. In the event they don't track their R&D costs by product or project, they must disclose and explain it.

Numerically, companies should be cautious when disaggregating their R&D expenses; the total of costs broken out must reconcile to the total R&D expense amount as presented in the Statements of Operations.

As with the MD&A section, if there have been any material fluctuations in R&D expenses across different periods, companies must identify and discuss the specific factors that led to such changes. Here, product- or program-specific breakdown is critical in helping companies identify the root causes for changes in expenses and build the foundation for such discussion.

The point of these comments is straightforward. R&D is foundational for life sciences companies and innovation requires funds. As product pipelines, research agendas and process deliveries grow, the scope, variety, and variability of R&D expenditure also grows. Regulatory developments add new reporting. To meet these changes, businesses must track R&D expenses in detail and be able to explain to the investing public their channels of spending.

Sample Comments

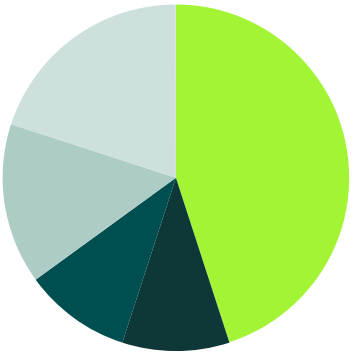
> *Certain amounts in your results of operations discussion are not the same as the amounts reported on your statements of operations. For example, your statement of operations reflects [dollar amount] million of R&D expenses, whereas your discussion refers to [another dollar amount]. Please revise as necessary. It also appears there was a significant increase in your R&D expenses in fiscal [year]. Please provide more details about your R&D expenses for each period presented, including but not limited to quantification by product/program, as well as by the nature of the expenses. To the extent that you do not track expenses by product candidate, please disclose as such. In addition, disclose the specific reasons for significant changes in R&D expenses as well as other expenses each period. Refer to Item 303 of Regulation S-K.*

> *We note you disclose R&D expenses by type of expense. Please expand your disclosure in future filings to provide the costs incurred during each period presented for each of your key R&D programs. If you do not track your R&D costs by program, please disclose that fact, and explain why you do not maintain and evaluate R&D costs by program. Provide proposed disclosure with your response.*

> *We note your R&D expenses consisted of several type of expenses. In future filings, please revise to provide more detail for your R&D expenses, including but not limited to the nature or type of these expenses.*

SEC REPORTING

FIGURE 21: Number of Comments for Forms 10-K, 10-Q, and 20-F Filings
By SEC Reporting Subcategory



2021-2022

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

20 Total Comments

2022-2023

37%	Certifications
7%	Discrepancies
15%	Filing of Exhbits and Other Material
30%	Other
11%	Updated Disclosures

27 Total Comments

Comments related to process compliance saw a slight decline this period, constituting 13.1% of the Forms 10-K, 10-Q, and 20-F mix as opposed to the 14.5% share in 2021–2022. Despite this drop, the significance and focus of this category remained intact.

Like the prior period, most comments were directed at certifications. Companies were largely required to revise their Section 302 certifications to include the introductory language in paragraph 4 referring to their internal control over financial reporting (ICFR) as well as paragraph 4(b), which referred to the design of internal reporting. Meanwhile, for Section 906 certifications, they were asked to revise and refer to the correct fiscal year.

Other comments requiring disclosures focused on:

- Filing of requisite exhibit material

- Reconciling discrepancies in facts and erroneous figures
- Including necessary audit reports that address any adjustments done to prior-period financial statements
- Ensuring compliance with sectional items Regulation S-K and Regulation S-X

Procedural compliance is just as important for public filers as for pre-IPO applicants. Companies must meet all sectional requirements for their relevant forms and provide sufficient disclosures throughout.

Sample Comments

> *Please amend your filing to revise the Section 906 certifications to include the correct year of your Form 10-K, for the period ended December [year].*

> *This annual report is your second annual report under Section 13(a) or 15(d) of the Exchange Act. The Section 302 certifications provided continue to omit paragraph 4(b) and the introductory language in paragraph 4 referring to internal control over financial reporting. Please provide corrected certifications in an amended filing that contains only the cover page, explanatory note, signature page and paragraphs 1, 2, 4 and 5 of the certifications. Please consider the guidance of Regulation S-K Compliance and Disclosure Interpretations Question 246.13.*

> *Please file all exhibits required by Item 601 of Regulation S-K with your amended 10-K.*

OTHER DISCLOSURE TOPICS

RISK DISCLOSURES

Comments related to risk-based disclosures made up 9.2% of total comments in 2022–2023, registering an increase from a share of 5.8% in 2021–2022.

The nature of SEC scrutiny was largely focused on China-based companies, which stemmed from the Division of Corporation Finance's specific guidance on disclosure obligations. The comments came from Section 2 of the illustrative sample letter shown above in the Entity Background chapter.

Companies were asked to disclose any significant legal, regulatory, liquidity, enforcement and operational risks associated with being based in or having most of the company's operations in China. This includes:

- Risks arising from the changing legal system
- Risks arising from government control
- Whether these risks could result in a material change in operations or the value of the securities registered for sale
- How statements or actions by China's government on key matters may impact the company's ability to conduct business

This included disclosures related to a possible delisting risk due to prohibition under HFCAA if the PCAOB determines it can't inspect or fully investigate the company's auditors.

Given the prominence of specified disclosures for China-based companies, which increased entity-related comments for public filers this period, risk-based disclosures is of unparalleled importance. Concerned public filers should carefully review the disclosure mandates and contact their industry office for more information.

Sample Comments

> *Provide prominent disclosure about the legal and operational risks associated with being based in or having the majority of the company's operations in China. Your disclosure should make clear whether these risks could result in a material change in your operations and/or the value of the securities you have registered for sale or could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless. Your disclosure should address how recent statements and regulatory actions by China's government, such as those related to the use of variable interest entities and data security or anti-monopoly concerns, have or may impact the company's ability to conduct its business, accept foreign investments, or list on a U.S. or other foreign exchange.*

> *Please disclose the risks that your corporate structure and being based in or having the majority of the company's operations in China poses to investors. In particular, describe the significant regulatory, liquidity, and enforcement risks. For example, specifically discuss risks arising from the legal system in China, including risks and uncertainties regarding the enforcement of laws and that rules and regulations in China can change quickly with little advance notice; and the risk that the Chinese government may intervene or influence your operations at any time, or may exert more control over offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in your operations and/or the value of your securities. Acknowledge any risks that any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.*

> *Given the Chinese government's significant oversight and discretion over the conduct of your business, please revise to highlight the risk that the Chinese government may intervene or influence your operations at any time, which could result in a material change in your operations and/or the value of your securities. Also, given recent statements by the Chinese government indicating an intent to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers, acknowledge the risk that any such action could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.*

INTERNAL CONTROL OVER FINANCIAL REPORTING

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.

Comments related to ICFR made up 5.8% of these filings in 2022–2023, staying in line with the previous period.

Like 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 its 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

> *In accordance with Item 308 of Regulation S-K, please amend your filing to provide management's annual report on internal control over financial reporting. Ensure you include a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting for the registrant. Also, include management's assessment of the effectiveness of the registrant's internal control over financial reporting as of the end of the registrant's most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective. Refer to Item 308(a)(1) and (3) of Regulation S-K.*

> *We also note that you have had material weaknesses in your internal control over financial reporting since [year] that have not been remediated. Please revise to clarify what specific steps remain to be completed in your remediation plan. Also, revise to disclose how long you estimate it will take to complete your remediation plan and disclose any associated material costs that you have incurred or expect to incur.*

REVENUE RECOGNITION

Comments related to companies' revenue recognition policy made up 5.3% of total Forms 10-K, 10-Q, and 20-F comments, registering a slight increase from a share of 5.1% last period.

SEC scrutiny was tied to the adoption of guidelines under Accounting Standards Code (ASC) 606, which states that an entity should recognize revenue when it transfers goods or services to a customer in an amount in which it expects to be entitled to receive from the customer.

Filers were asked to thoroughly review their customer contracts, especially multiple element arrangements, and have their disclosures:

- Identify the promised goods or services under the agreement
- Explain which promised goods and services are distinct performance obligations and which have been combined
- Quantify the total transaction price and explain how it's determined
- Disclose how the total transaction price is allocated among various performance obligations and the amounts that have been recognized over the year. This includes establishing the point of control and when the good or service becomes satisfied or earned.

Clarity is essential for compliance with ASC 606. Companies must have clear-cut procedures for establishing completion of their performance obligations and recognition of revenue that are consistent for all types of contracts.

Sample Comments

> *Please revise your disclosures to provide the information required by ASC 606-10-50-12 through 50-12A for the performance obligations for your [agreement] and research services along with the disclosures required by ASC 606-10-50-13 through 50-15 for those contracts with multiple performance obligations, how you determined the transaction price and the significant judgments made in estimating the transaction price as it relates to variable consideration in accordance with ASC 606-10-50-17 and 50-20, and when the performance obligations are satisfied in accordance with ASC 606-10-50-18 through 50.*

> *We note your contracts may include multiple performance obligations. Please revise your revenue recognition disclosure in future filings so that users can understand any impact between recurring and non-recurring revenues from your allocation of the transaction price. In this regard, please disclose the qualitative and quantitative information about the significant judgments, and changes in judgments, that significantly affect the determination of the amount and timing of revenue, as set forth in ASC 606-10-50-1(b) and 606-10-50-17(b). Please provide us any proposed disclosure.*

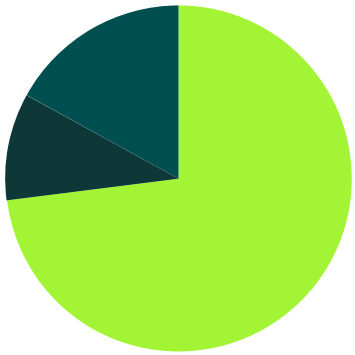
MARKET CAPITALIZATION RANGE

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

Over 85% 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, 12% were directed toward those with market capitalization between $500 million and $1 billion while 3% pertained to those greater than $1 billion but less than $2 billion.

Smaller companies continued to attract the greatest scrutiny.

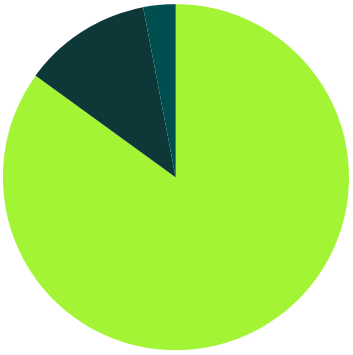
FIGURE 22: Breakdown of Forms 10-K, 10-Q, and 20-F Comments
By Market Capitalization Range ($B)



2021-2022

73%	$0 – $0.50
10%	$0.51 – $1.00
17%	$1.01 – $2.00

138 Total Comments

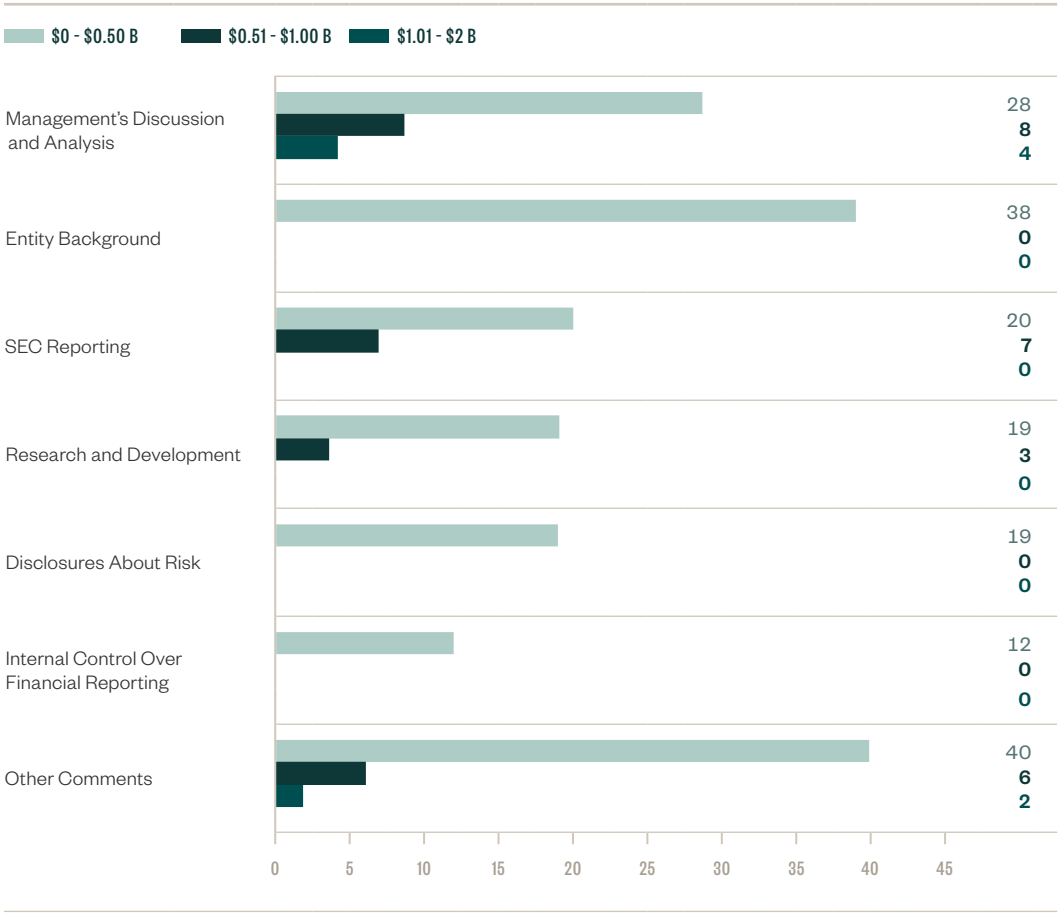


2022-2023

85%	$0 – $0.50
12%	$0.51 – $1.00
3%	$1.01 – $2.00

206 Total Comments

FIGURE 23: Trends in SEC Comment Categories by Market Capitalization
2022-2023 by Number of Comments



As in 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.

The negative correlation can be attributed to a difference in experience and resources. Registrants filing statements for the first time might not be as well-versed in regulatory compliance and therefore attract more SEC comments and require more iterations.

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

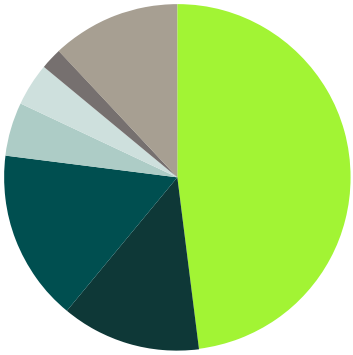
The current market-capitalization distribution among life sciences companies indicates there may be a greater number of small-sized filers than larger ones, which also impacts the distribution of SEC comments to each category.

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

SECTION FOUR

Subindustry Trends

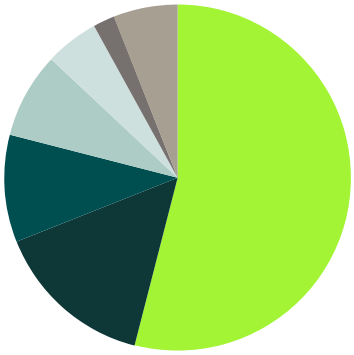
FIGURE 24: Percentage of Comments
By Subindustry



2021-2022

48%	Pharmaceutical Preparations
13%	Surgical and Medical Instruments and Apparatus
16%	Biological Products (No Diagnostic Substances)
5%	Medicinal Chemicals and Botanical Products
4%	Commercial Physical and Biological Research
2%	Electromedical and Electrotherapeutic Apparatus
12%	Other Subindustries Combined

1,625 Total Comments



2022-2023

54%	Pharmaceutical Preparations
15%	Surgical and Medical Instruments and Apparatus
10%	Biological Products (No Diagnostic Substances)
8%	Medicinal Chemicals and Botanical Products
5%	Commercial Physical and Biological Research
2%	Electromedical and Electrotherapeutic Apparatus
6%	Other Subindustries Combined

693 Total Comments

Pharmaceutical preparations continued to attract SEC focus. Its share of total comments increased from 48% in 2021–2022 to 54% this period. 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.

Surgical and medical instruments and apparatus was the next most significant subindustry sector with an aggregate comment share of 15%, followed by biological products at 10%.

As in previous years, there has been a shift in dynamics between the surgical and medical instruments and apparatus and biological products sectors. While the ratio of comments for surgical and medical instruments and apparatus went up by 2% from the previous study, that for biological products came down by 6%. This pattern of increase and decrease occurred for the last four consecutive periods.

Medicinal chemicals and botanical products was the subindustry with the fourth largest comment share with 8%. SEC focus increased from the previous report.

Comments on commercial physical and biological research which increased from the previous study, accounting for a share of 5% in 2022–2023.

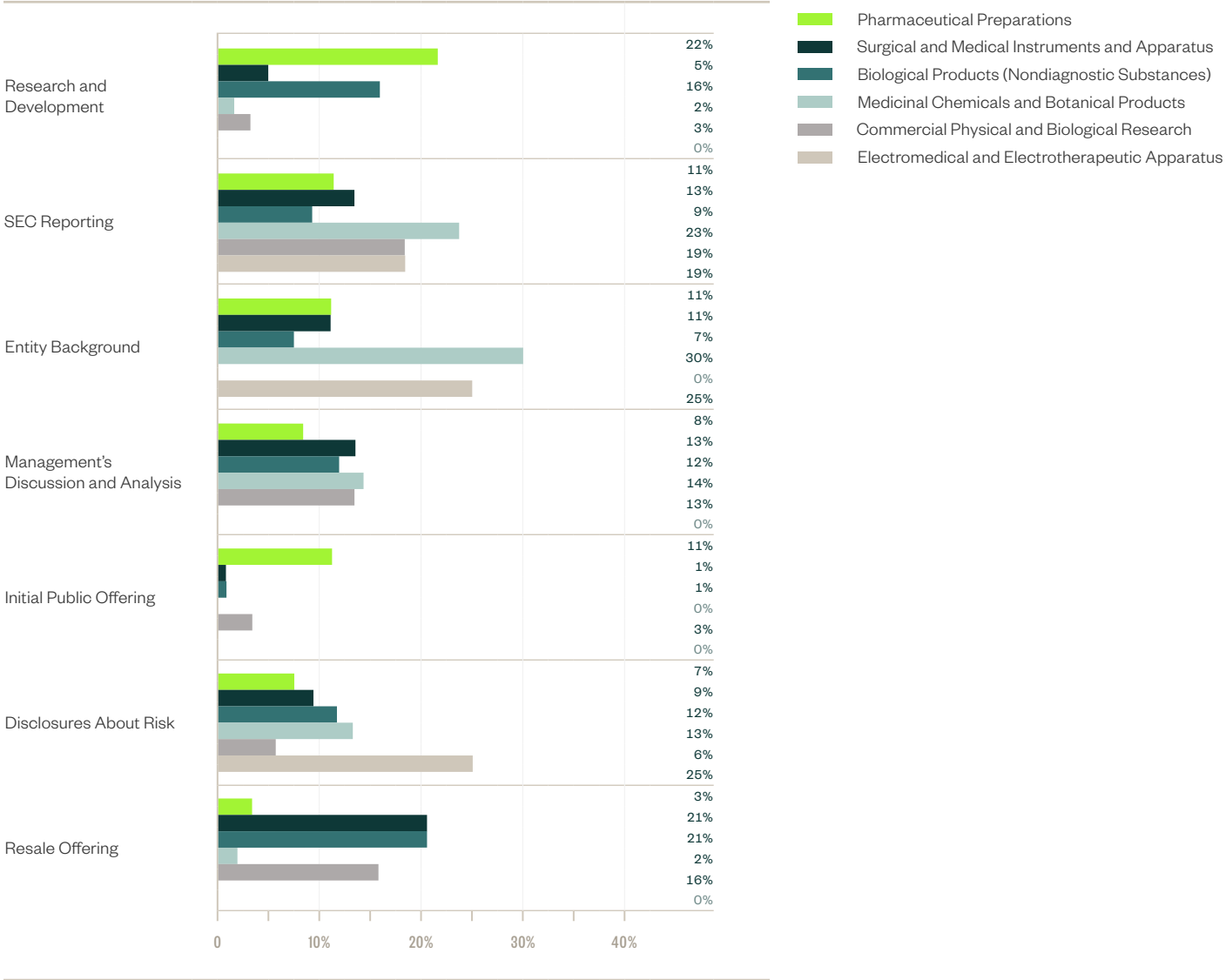
Other subindustries had smaller shares of less than 3% each.

X-ray apparatus and tubes and related irradiation apparatus, which didn't attract any relevant comments in 2021–2022, received 16 comments this period.

NATURE OF COMMENT CATEGORIES

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

FIGURE 25: Share of Comment Categories
2022-2023 by Subindustry



Compliance is important for every company, regardless of subindustry sector. A simple filing mistake or disclosure error can attract scrutiny. Consequently, it's not surprising that comments related to SEC reporting, or process compliance, emerge as a key category for companies across subindustries every year. Comments in this area remained significant across subindustries, generally making up 10%–20% of the mix.

MD&A and risk-related disclosures are similar. These two categories are structural mandates, as stipulated in Regulation S-K, and apply to every subindustry. As a result, comments in these areas constitute a balanced spread across all types of companies each year.

R&D disclosures are critical and are a key focus of SEC examination. However, the comment spread is skewed toward the pharmaceutical preparations and biological products subindustries. This period, R&D-related comments in these two sectors constituted 22% and 16% of the mix, respectively. The reasoning is intuitive. While R&D is inherently important for all life sciences companies, its role in pharmaceutical preparations and biological products tends to be more extensive.

These two subindustries often deal with complex development pipelines that involve numerous clinical studies and long gestation periods. They can be required to make expansive disclosures around these areas and transparently map out the time and capital needed for those processes.

Entity-related disclosures made up a large portion of SEC comments for medicinal chemicals and botanical products, constituting more than 30% of the mix. This trend has carried over from the last period, when this subindustry saw a jump in entity background comments. Electromedical and electrotherapeutic apparatus continued to earn more comments in this area with a 25% share.

This period also saw an influx of comments related to resale offerings. SEC scrutiny was focused on surgical and medical instruments and apparatus, biological products, and commercial physical and biological research. This distribution is not dependent on industry dynamics. Any company filing a resale offering with incomplete disclosures can attract SEC comments, regardless of its business operations.

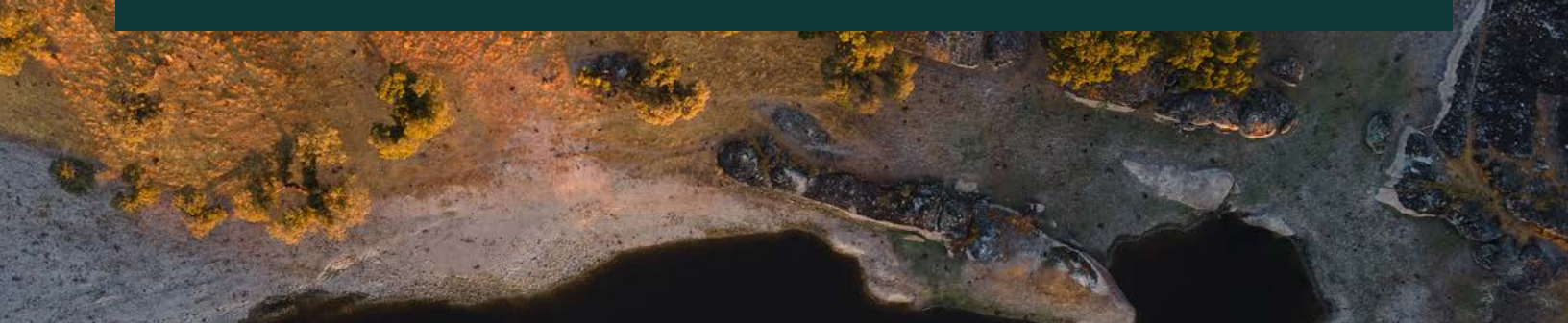
As a rule, there does exist a huge degree of dynamism across comment categories. Certain topics may attract more scrutiny one year and less the next. For example, companies in electromedical and electrotherapeutic apparatus saw no comments in R&D this period, but a 33.3% share last period, while scrutiny on risk-based disclosures catapulted.

Surgical and medical instruments and apparatus had more MD&A comments this period as compared to the past period, plus more scrutiny pertaining to resale offerings. However, R&D comments came down considerably over the last one-year period.

This depends on both market dynamics and timing, which can highlight efforts companies are making to address emergent issues in their filings.

Companies should track market specifics and challenges or sensitivities that require additional clarification. They also need to monitor changing macro-conditions on both global and local levels, the effects on the business, and if further disclosure is needed.

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



SECTION FIVE

Conclusion

The past year has seen a continuation of the dry spell in the IPO landscape. This is causing life sciences companies to develop new financing strategies that help them remain viable going into 2024.

Macroeconomic conditions in the marketplace also played a role in life science companies' financial strategies and performance. Combined with economic uncertainty arising from geopolitical events in Ukraine and Palestine, this unstable economic environment will continue to test life companies' financial agility and flexibility.

Capital financing will remain crucial to tackling these challenges. In a market where financing is tight, it's crucial for companies in the IPO ecosystem to stay ahead of the filing process and structure tailor-made offerings that capture investor interest. This means remaining as transparent and informative as possible in all public filings to secure not just long-term capital but unwavering public confidence.

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 gain momentum and equity financings remain a core 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 2022–2023 report, the SEC sought clarity from companies on a host of issues, ranging from adequate disclosures and insightful discussions to a 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 and long product pipelines, and regulations, disclosure in these areas is important.

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

At the same time, new areas of focus may emerge due to changing market dynamics and new legal mandates. A similar trend was seen in this 2022–2023 study, when comments related to resale offerings and foreign exposure rose considerably over one year. It's recommended that filers be proactive with these changes and make requisite disclosures beforehand to avoid lengthy scrutiny.

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

All these disclosures must be made within stipulated SEC guidelines. Adherence to Regulations S-K and 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 have questions on how to prepare your company for its IPO, contact a Moss Adams professional.

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