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Under the Microscope

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

2023-2024

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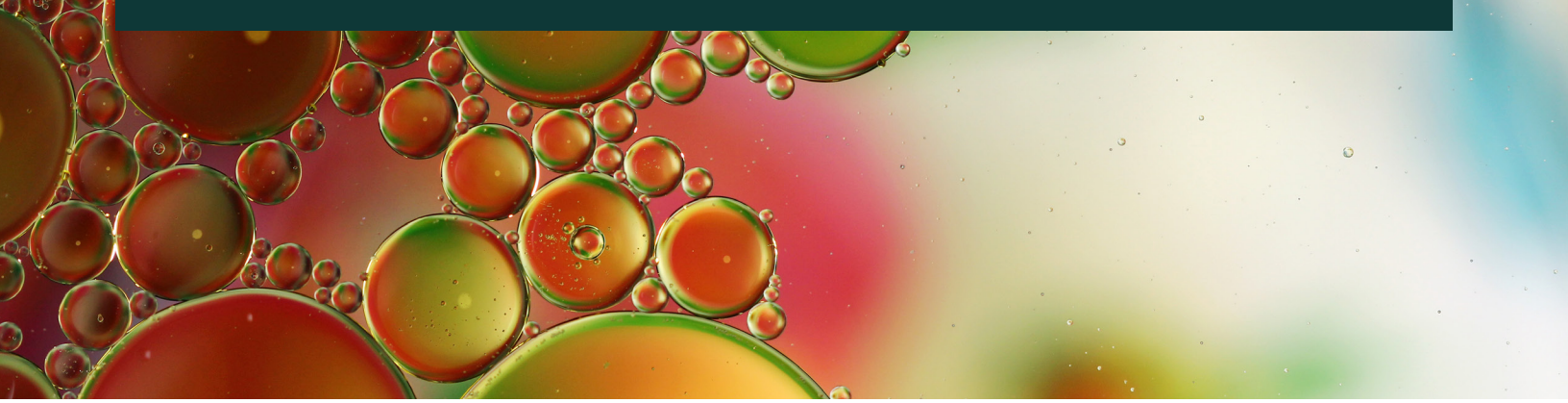


INDUSTRY OVERVIEW

Initial public offering (IPO) activity saw a positive turning point in 2024. The dry spell of 2022 and 2023 finally came to an end, with a steady momentum being established in the first three quarters. This rebound is expected to further pick up pace in 2025.

PERFORMANCE RECAP

Through Q3 2024, there was a 16% increase in the number of US IPOs and 86% increase in proceeds compared to the same timeframe in 2023. 2024 IPO proceeds have already outperformed all of 2023 and 2022 bolstered by non-US companies going public in the US.

In terms of sectoral performance, life sciences and technology companies have been particularly active, showing a significant increase in private equity (PE) and venture capital (VC) backed IPOs.

Specifically in life sciences, the growth of IPOs was driven by new drug development and advances in cell and gene therapy, facilitated by emerging technologies such as artificial intelligence (AI) and CRISPR. These areas, especially the use of AI in drug development, are seeing significant breakthroughs and attracting substantial investment. Despite the record volumes of 2020-2021 still being off the charts, the sector has witnessed a steady increase in deal numbers and average deal sizes. This reflects renewed yet cautious investor confidence on concrete clinical solutions that generate results.

This isn't to say this growth will be immune to external disturbances. Geopolitical tensions and economic slowdowns will continue to influence investor sentiment. Consequently, attractive companies will be those that aim for feasible targets, demonstrate a clear path to profitability and outline a clear mitigation strategy in the advent of fluctuations.

Regulatory stability is equally pivotal in keeping markets stable. While the presidential election did bring a bout of volatility, this uncertainty is expected to be short-lived. Greater governance clarity upon the completion of the election cycle, including appointments in the SEC, coupled with a decrease in interest rates, should give the capital markets a strong headway in 2025 as recent discussions of tariffs stabilize.

KEY INDUSTRY TRENDS

Innovation remains at the forefront of life sciences. However, it's not only the innovation of products but the methodology behind developing such products that has gained widespread importance.

Digital practices are continuing to re-engineer processes, with the Food and Drug Administration (FDA) noting that AI and machine learning (ML) will have a critical role in drug development. A wide range of studies suggest that AI has most frequently been used in understanding diseases and small molecule design and optimization from 2018 to 2022, especially amid the acceleration of vaccines and antibodies driven by the pandemic.

Meanwhile, the use of AI in biologics development is also increasing, given the sophistication of algorithms, mature computing power, greater data availability, and evolution of discovery workflows.

Rapid and Rigorous R&D

The FDA's Center for Drug Evaluation and Research (CDER) approved 55 novel drugs in 2023, which is the highest number approved between 2019 and 2022. It further investigated expanding the use or patient population of previously approved drugs. Specifically, the CDER took actions to make three opioid overdose reversal drugs available without a prescription to increase access to life-saving therapies, as well as new dosage forms in this regard. This aligns with its broader Overdose Prevention Framework.

Concurrently, the CDER continued to focus its approvals on a wide range of other conditions, helping patients with few or no treatment options and those with rare diseases. In fact, 51% of the 55 drugs approved received orphan drug designation since they target rare diseases including:

- Friedreich's ataxia
- Candidemia and invasive candidiasis
- Rett syndrome
- CHAPLE disease
- Paroxysmal nocturnal hemoglobinuria
- Activated phosphoinositide 3-kinase delta

Process efficiency also improved as the CDER met or exceeded its Prescription Drug User Fee Act (PDUFA) goal dates for 49 of the 55 approvals. Moreover, it approved 84% of the drugs on the first cycle.

A similar performance snapshot holds true for 2024, with over 50 approved drugs included in the running list as of the end of the calendar year.

This highlights the FDA's objective to balance regulatory scrutiny with market timeliness, to meet patient needs. Firms with breakthrough solutions for unmet needs are encouraged to pursue an expedited review pathway, provided that their clinical development phase is robust and holistic enough to satisfy all safety parameters.

Such makes R&D a pivotal business function that needs to be meticulously planned and carefully explained in all public communications.

Similarly, this focus was also observed in the 2023-2024 Securities and Exchange Commission (SEC) filings, with R&D, which has always been a key topic of focus, continuing to come under added scrutiny.

Within a majority of the studied filings 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, as well as finished products, making sure not to make superfluous claims that can otherwise appear to be misleading. Such disclosures become even critical in public filings, as well as prospectuses leading up to an IPO.

Like previous periods, SEC examination of information symmetry, adequacy, and effectiveness continued to be a key focus in 2023-2024, with many registrants asked to re-evaluate the quantum and language of their statements — especially those made in relation 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.

Ongoing Updates

Compliance is never a stationary aspect, and the SEC continues to publish enhanced disclosure requirements from time to time. For example, on October 10, 2023, the SEC adopted amendments to certain rules that govern beneficial ownership reporting, generally shortening the filing deadlines for initial and amended beneficial ownership reports filed on Schedules 13D and 13G as well as requiring that the filings be made using a structured, machine-readable data language.

Meanwhile, on January 24, 2024, it adopted new rules and amendments to enhance disclosures and provide additional investor protection in IPOs by special purpose acquisition companies (SPACs) and in subsequent business combination transactions between SPACs and target companies (de-SPAC transactions). This helps align the rules of SPACs with those of traditional IPOs.

Concurrently, interoperability remains a pivotal area of focus and improvement. On August 2, 2024, the SEC proposed joint data standards under the Financial Data Transparency Act of 2022 that would establish technical standards for data submitted to certain financial regulatory agencies. This would promote interoperability of financial regulatory data across the agencies by establishing common identifiers for entities, geographic locations, dates, and certain products and currencies.

Managing Changing Procedural Requirements

Changing trends and issues play into changing regulations. The SEC's various amendments and proposals are efforts to keep up with dynamic market conditions. The aim of these changes is to ensure consistent and complete information delivery throughout new developments and encourage stable growth.

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

SEC COMMENT LETTER REPORT

RATIONALE

The objective of SEC comments is to preserve market confidence by helping companies prevent discrepancies and bring greater transparency to investors. The rationale of this SEC comment letter report is to identify, understand, and analyze comments made by the SEC in the past, to derive insights and encourage proactive preparedness for SEC registrants.

This report specifically examines SEC comments related to Forms S-1, 10-K, 10-Q, and 20-F filings in 2023–2024, identifying possible patterns and changes in SEC staff focus in relation to the 2022–2023 study.

METHODOLOGY

To perform our analysis, we categorized all SEC comments issued to companies in select life sciences subindustries during the review period. The following subindustries were covered in our analysis, identified by the SEC's Electronic Data Gathering, Analysis, and Retrieval system (EDGAR) Standard Industrial Classification (SIC) code.

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

Because middle-market companies were the focus of our study, we excluded from our research and assessment comments related to companies with market capitalization greater than $2 billion on the dates of analysis, which were December 12-13, 2024.

Our analysis included comments filed on the SEC EDGAR database during the period from May 1, 2023, to April 30, 2024, which we'll refer to as 2023–2024.

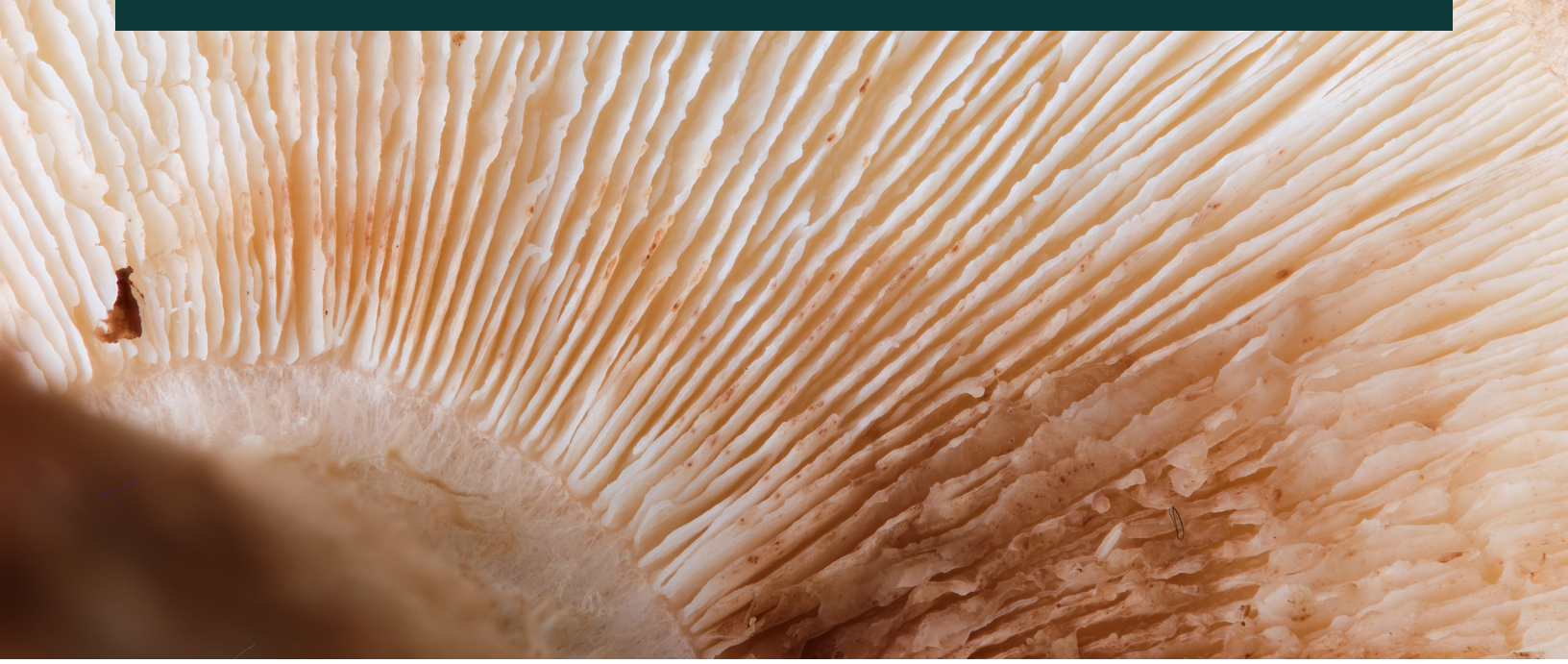
To achieve a fair and objective assessment of the data, we considered only the first instance of an SEC comment letter for an individual filing, given that, in subsequent instances, letters from the SEC often contained comments of similar nature to those found in the first iteration, or enhanced the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

While the period of analysis under our current and previous reports, known as 2023–2024 and 2022–2023, 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 2022–2023 to 2023–2024 exceeded the mean variance in that subset to be significant variances over the last two years.

For example, out of the 487 comments directed toward Form S-1 filings in 2022–2023, 82 were related to R&D, amounting to a ratio of 16.84%. The same ratio increased to 22.32% in 2023–2024, an increase of approximately 5.48 percentage points. 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 research and development-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

In total, there were 727 SEC comments issued in response to Forms S-1, 10-K, 10-Q, and 20-F filings in 2023–2024, a 4.9% increase from the 693-comment count in 2022–2023. This slight rise is consistent with an improved IPO market during the period.

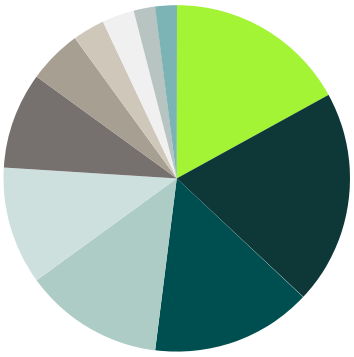
Comments were largely spread across key comment categories. Those related to R&D were the most prominent with a 19.8% share. Like the previous study, the SEC continued its focus on ensuring complete disclosure when it comes to companies' clinical trials and studies and requiring clarity and objectivity regarding developmental products and pipelines. A clear representation of R&D expenses also remained critical as in the previous 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 major category with a share of 15.1%, with majority comments—as in the 2022-2023 study—requiring companies to make requisite disclosures throughout their prospectuses, including filing all material information and compliant certifications. In addition, disclosures regarding foreign jurisdictions that prevent inspections emerged as focal point of SEC scrutiny this period for post-IPO filers.

This was followed by comments requiring disclosure of entity background, management's discussion and analysis (MD&A), current or anticipated risks related to the business, as well as details on resale offerings.

Information around initial public offering prospectuses, patents, licensing agreements and material contracts collectively constituted another significant chunk of SEC scrutiny, followed by various other comments targeting firm-specific controls and regulatory features.

FIGURE 1: Overview of SEC Comment Categories



17%	Other Comments[3]
20%	Research and Development[1]
15%	SEC Reporting/Process Compliance[2]
13%	Management's Discussion and Analysis
11%	Entity Background
9%	Resale Offering
6%	Disclosures About Risk
3%	Patents
3%	Licenses
2%	Material Contracts
2%	Initial Public Offering

727 Total Comments

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

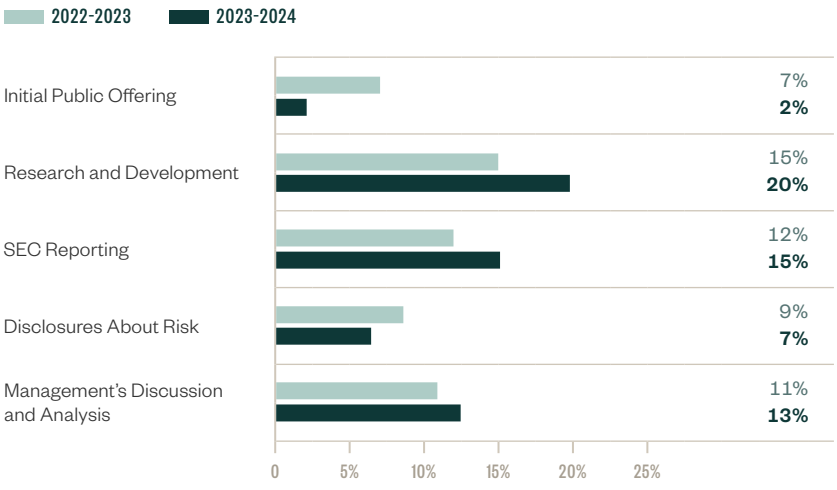
[2] Comments related to process compliance tend to be more administrative and formulaic, but because of the sheer volume of such comments, companies have an opportunity to significantly reduce filing delays by understanding the nature of scrutiny under this topic and taking the appropriate steps to comply.

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

SIGNIFICANT SHIFTS

Some topics saw a slight-to-significant shift in focus when compared to 2022-2023, with the positive or negative variance measured as a ratio to the total number of comments. This included categories such as initial public offering, R&D, process compliance, disclosures about risk, and MD&A.

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



Comments related to R&D saw a sharp increase of 4.8%, while those related to process compliance and MD&A rose steadily by 3.1% and 1.5% respectively.

Contrastingly, comments related to initial public offering plummeted by 4.9% while those related to risk-based disclosures dipped slightly by 2.2%.

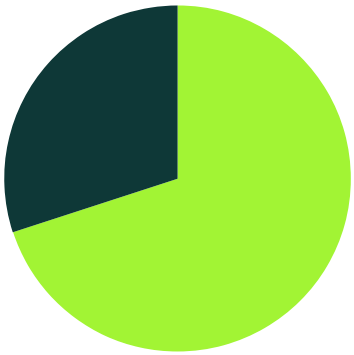
The mean variance of overall comments decreased from 2.6% in 2022-2023 to 1.8% this period, given only a slight shift in the total number of comments and categorization spread. Except for certain categories such as initial public offering and process compliance—which saw some fluctuation in overall focus and subtopics—the nature and composition of comments over the last two periods remained fairly consistent.

COMPOSITION BY FILING TYPE

Like prior years, Form S-1 filings continued to lead in relation to SEC scrutiny. Of the 727 total comments analyzed in the study, roughly 75%—542 comments—were directed at Form S-1. This is a slight increase from a share of 70% in 2022–2023.

The remaining 25% of comments were directed toward Forms 10-K, 10-Q, and 20-F filings.

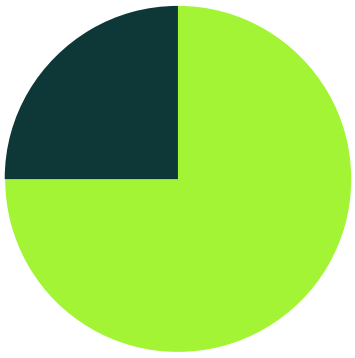
FIGURE 3: Percentage of Comments
By Filing Type



2022-2023

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

693 Total Comments



2023-2024

75% Form S-1 Filings
25% Forms 10-K, 10-Q, 20-F Filings

727 Total Comments

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

Pre-IPO applicants were asked to elaborate on their product pipeline, solution breakthroughs, potential market standing and anticipatory risks, and clarify details about the offering terms and price. SEC scrutiny was particularly focused upon clinical trials and studies, requiring applicants to present unambiguous disclosures on their research methodologies, types of trials undertaken and core findings or results.

Comments related to resale registrations—that emerged as a key area of SEC focus last period—continued to remain in focus. Relevant Form S-1 filers were asked to provide more details on their 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.

This period also saw a significant number of comments being directed to Disclosure Regarding Foreign Jurisdictions that Prevent Inspections, pursuant to the SEC's adoption of amendments that revised Forms 20-F, 40-F, 10-K, and N-CSR to implement the disclosure and submission requirements of the Holding Foreign Companies Accountable Act.

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

NUMBER OF COMMENTS ISSUED

The number of SEC comments this year has largely stayed in line with the drastic drop witnessed in the previous period. Total SEC comments directed toward all four filings—Forms S-1, 10-K, 10-Q, and 20-F—have only risen by a meager 4.9% from 2022-2023 to 2023-2024 in comparison to a 57.4% drop seen last period from 2021-2022 to 2022-2023.

This fall in comments can be attributed to the stagnant IPO market that, although having improved in 2023-2024, has still not reached its full momentum. SEC comment letters on draft prospectuses for IPOs are the ones that contain the greatest number of comments, given they are directed toward applicants going public for the first time with sparse procedural compliance. Intuitively, if companies haven't been filing for IPOs in the recent dry spell and consequently not submitting their prospectuses, the potential for the SEC to issue comments will be lower.

This isn't to say these draft registration statements are the only source of Form S-1 comments. Companies can still attract comments on their amended and officially filed Form S-1 for an IPO, as well as on iterations concerning resale offerings. While the comments may be typically lesser than those initial prospectuses, the scope for scrutiny very well exists. This balanced mix was witnessed in this period's study.

Many comment letters were also directed toward other filings such as Forms S-3 and S-4, highlighting the ongoing nature of the SEC's review. In fact, public filers within the ambit of this study—Forms 10-K, 10-Q and 20-F—continued to attract a substantive number of comments, increasing in absolute numbers from the 2021-2022 study, despite the 57.4% drop in total comments from 2021-2022 to 2022-2023.

SECTION TWO

Trends In S-1 Filings

As expected, Form S-1 filings claimed more SEC attention than other filing types, making up 542 comments. That's 75% of the total 727 comments under review, a slight increase from 2022–2023, when Form S-1 comments made up 70% of the mix.

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

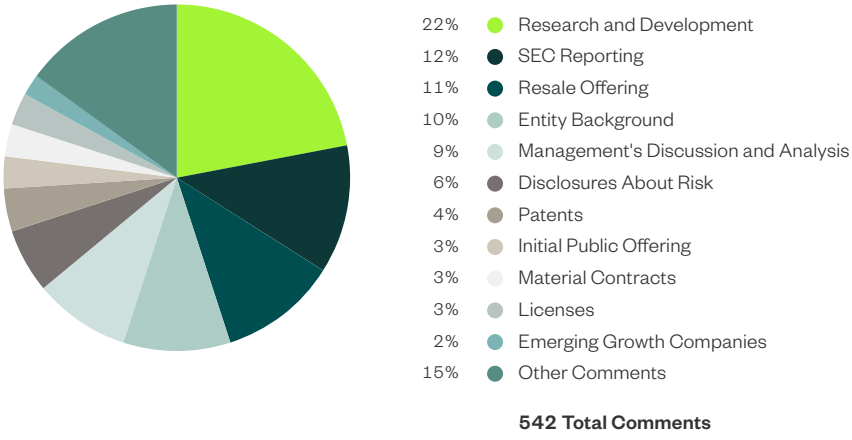
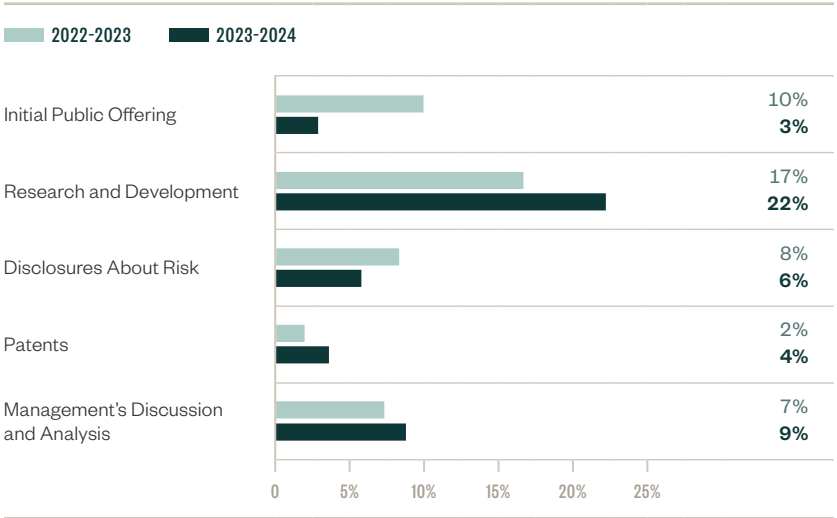


FIGURE 5: Significant Shifts in SEC Focus for Form S-1 Filings
By Ratio of Comments



In our comparative analysis, we noted categories that made slight to significant shifts relative to the 2022–2023 study. Comments related to R&D saw a significant

increase of 5.5% while those related to MD&A and patents rose steadily by 1.5% and 1.6% respectively. Contrastingly, focus on IPOs greatly plummeted by 7.1% while risk-based disclosures saw a slight decline of 2.5%.

The mean variance for Form S-1 comments decreased from 2.8% in 2022–2023 to 1.8% this period, highlighting lesser movement in the categorization spread.

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

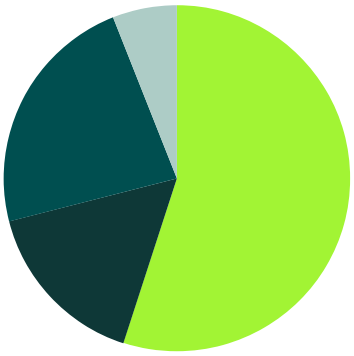
RESEARCH AND DEVELOPMENT (R&D)

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

2022-2023

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

82 Total Comments



2023-2024

55%	Clinical Trials and Studies
16%	Product Pipeline
23%	Products and Services
6%	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

With the IPO market showing signs of recovery, it's more than critical for companies to maintain comprehensive and transparent R&D disclosures that keep market confidence in-tact, including:

- Communicating objectively about developmental pipelines on a candidate-by-candidate basis
- Describing all clinical trials undertaken and being undertaken from an observational lens
- Disclosing any interactions made with the FDA on pursuing an expedited pathway
- Acknowledging any regulatory and feasibility challenges in the process

The FDA continues to encourage the development of quality solutions that target unmet or rare diseases or those that are presumably safer and more patient-friendly than existing ones in the market. Consequently, many companies are claiming such breakthrough therapies as a key differentiating factor in their prospectuses. In such cases, deciphering the validity of these statements and outlining their actual market acceptance is pivotal.

Given the criticality of these issues, R&D prompted the greatest number of Form S-1 comments this period, making up 22.3% of the mix. This is a significant increase from a share of 16.8% in 2022–2023.

Within this category, comments directed toward clinical trials and studies stood out with a 55.4% share. Comments related to products in development and product pipelines followed, at shares of 23.1% and 15.7% respectively.

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

CLINICAL TRIALS AND STUDIES

Similar to prior periods, clinical trials and studies stood as the most prominent subcategory in R&D in 2023–2024, making up 67 comments, or approximately 55.4%. This is a further increase from a share of 40% in 2022-2023.

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

Many companies were further requested to remove any conclusory statements regarding the trial results or their meaning and instead focus on the specific factual details of the studies, including quantitative information regarding the range of results observed and describe the results using objective data and/or terminology based on the trial endpoint(s). This especially includes avoiding terms such as "safe", "breakthrough" or "compelling" when describing trial results, regardless of how promising they are, as they give off a subjective positioning and

inference regarding FDA approval. Registrants can state, if it's the case, that there have been no serious adverse events (SAEs) and continue to evaluate the data observed.

Similarly, to the extent that an SAE has occurred, companies must clearly disclose the event and the number of affected patients.

Statistical significance is another important element. The SEC asked companies to disclose whether their referenced studies were designed to be powered for statistical significance. If so, they were asked to provide the p-values for measurement, discuss how these values are used, and explain how statistical significance relates to the FDA standards of efficacy.

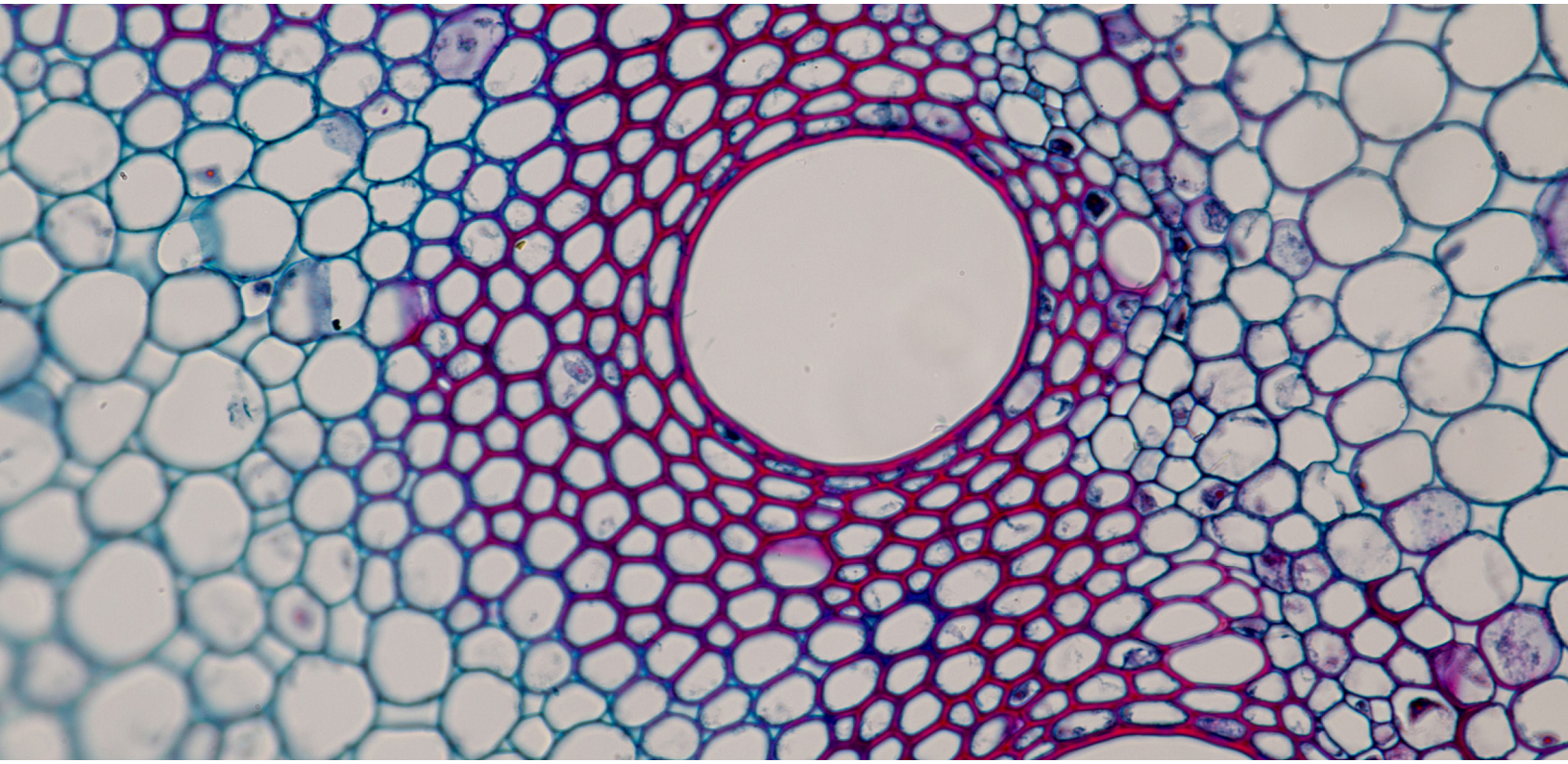
When comparing trial results where comparison isn't based on head-to-head studies, companies must concretely explain their reasoning and whether these comparisons can also be relied on to obtain other approvals.

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.

Concurrently, if a company believes its clinical trials or studies are strategically crafted for success or efficiency, it must objectively describe the basis for such claims and disclose whether it has had any discussions with the FDA regarding this and the outcome for the same.

Further, all graphics pertaining to either the study design and/or the representation of results must be clearly linked to the data with proper explanations.

Lastly, given that the use of expedited pathways for drug approval is in full swing, companies must be highly transparent if they've been permitted by the FDA to shorten any parameters of their trial. Statements that aren't backed by concrete FDA confirmation will not suffice.



Sample Comments

> *Please place any similar statements in context by disclosing that the FDA or other regulatory authorities may disagree with your clinical trial designs and interpretation of data or may not permit you to reduce the number of patients required. Please also revise to clarify whether the FDA has permitted you to reduce the number of patients in your currently active trials.*

> *Please revise this section to explain who completed the multiple preclinical models of [candidate name] referenced on [page number]. Also, please identify the "originator" that studied [candidate name] in two previous clinical trials for patients with MDD, when such trials were completed, and disclose the primary and secondary endpoints of such studies as well as the results as they relate to those endpoints.*

> *We note that you are collaborating with [partner name] to reformulate [candidate name] from its initial oral delivery method and are currently conducting a second Phase 1 trial in healthy human subjects studying transdermally delivered [candidate name]. You state on [page number] that you observed successful transdermal drug delivery at the desired concentrations in mini-pig studies. Please revise to present more detailed information regarding these animal studies, such as the number of animal models used, the number of tests conducted, the range of results or effects observed in these tests and how such results were measured. Alternatively, explain to us why this disclosure would not be material.*

> *Please revise the description of clinical trials to describe the objective results, rather than your conclusions. For example, rather than indicating that the [trial name] demonstrated a [percent] overall response rate, identify the clinical endpoints that lead you or [party name] to conclude that it was a positive response and indicate the number of such observations. For instance, was the overall response rate intended to indicate an elimination of all tumors, a reduction in the number of tumors, a reduction in size of the tumors, a decline in growth in the number of size of tumors, or some other measure?*

> *We note your discussion of statistical significance throughout the Business section. Please revise your disclosure to provide p-values for the results of each study that was powered for statistical significance. In addition, please disclose the primary and secondary endpoints for each trial, to the extent applicable, adverse events and whether the trials met the designated endpoints if the trial has concluded.*

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.

Comments related to product pipelines made up 15.7% of the R&D mix in 2023-2024, registering a moderate decline from the last period's share of 22%. Despite this fluctuation, the criticality of this area remains in-tact.

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.

The nature of each developmental phase must also be objectively considered. For example, if a company has listed two distinct phases of development in its pipeline when in reality, they both are meant to characterize pre-clinical work, this distinction is cosmetic and must be removed.

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 pipeline table to make the columns for each phase the same size.*

> *It appears that your current pipeline consists of clinical-stage assets that have been acquired or in-licensed, and that in certain cases the originators of such candidates progressed your candidates through certain phases of clinical development. Please add footnotes to your pipeline table to show which columns relate to work conducted by the company and which, if any, relate to the work of third parties.*

> *We note the inclusion of the [candidate names] and Discovery rows in the pipeline tables on [page numbers]. Please explain why you believe these product candidates are material to the company's operations at this time. In the event the company does consider each material, please provide more detailed disclosure in both the Summary and Business sections regarding each candidate. In the event these candidates are not material at this time, please revise the pipeline table to remove each row.*

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.

Comments in this topic made up 23.1% of total R&D comments in 2023–2024, a moderate decline from a share of 29.3% in 2022–2023. Despite this fluctuation, the criticality of this area remains in-tact.

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? • How will these components interact with other solutions already in the market? • 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/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? • Are there any external studies being referenced and compared? Are all comparisons based on head-to-head trials?
Intellectual property	• Is there any uncertainty whether claims in pending patent applications will be considered patentable? • Is there any reliance on intellectual property licensed from a third party? Possible implications as a result?
Statement of regulatory approval	• Are INDs submitted? If not, any rough idea of timelines? 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? • Is the product qualified for an expedited pathway to approval? What's the evidence? • 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? Sole supplier concerns?

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. This includes refraining from terms and phrases such as "high unmet medical need" or "an efficient path to registration as these statements can imply product candidates to be eligible for fast-track designation or priority review granted by the FDA.

Further, 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.

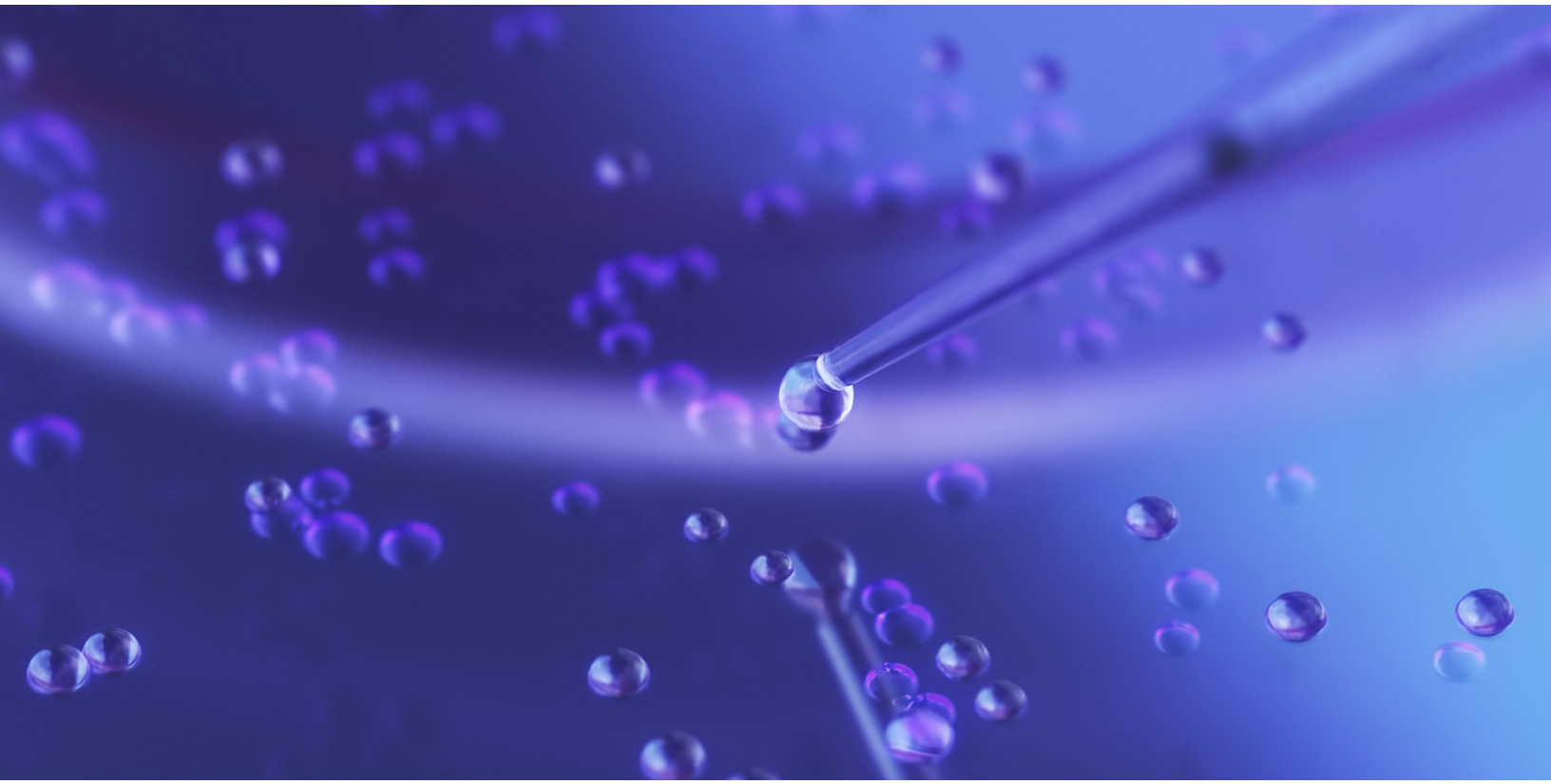
There's no procedural secret recipe for excelling in product-related disclosures. Making objective, comprehensive, and holistic disclosures can mitigate the scrutinizing comments.

Sample Comments

> *Please revise this section to explain, if true, that [candidate name] is being developed as a combination product due its patch formulation. Explain the implications of combination product status with respect to the regulatory approval process. Disclose whether or not you have had any conversations with or received any input from the FDA to date regarding the patch formulation of [candidate name], and if so, describe the outcome of such discussions.*

> *Please revise [page numbers] to disclose the significance of the FDA's determination that your [diagnostic name] is a non-significant risk device. Please clarify whether your companion diagnostic will require FDA medical device approval as you appear to suggest on [page number].*

> *We note your disclosure on [page number] highlighting your belief that [candidate name] will prove superior to existing treatments because you expect it will be less invasive, and will regenerate the disc, restore function and reduce pain without debilitating long-term effects. Given that you have not conducted human clinical trials, please revise to provide balance and context to your beliefs and expectations regarding the potential performance of the product under development.*



ENTITY-RELATED INFORMATION

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

2022-2023

16% Market
30% Products and Services
54% Other

43 Total Comments

2023-2024

18% Market
51% Products and Services
31% Other

55 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
- Description of any proprietary technology or approach that provides the company with a competitive advantage
- 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 was an aggregate of 55 comments pertaining to entity-related information this period, making up 10.1% of total Form S-1 comments. This is up from a share of 8.8% in 2022–2023.

Much of the SEC focus this period was concentrated around companies' product portfolios and market positioning. While comments related to other areas such as the legal structure and regulatory ambit persisted, they were substantially fewer in comparison to the prior two periods.

EXTERNAL ENVIRONMENT

Markets constantly evolve, and no business is immune to change. Issues such as macroeconomic fluctuations, geopolitical tensions and global policy actions continue to evolve in the backdrop, 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 18.2% of entity-background comments this period, registering a slight increase from a share of 16.3% in 2022–2023.

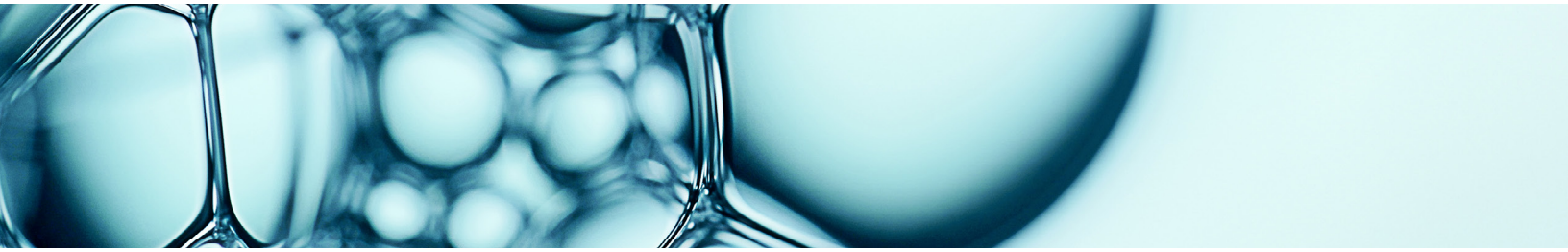
As in prior years, the SEC continued to require registrants for the following:

- 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

> *We note your statistics on [page number] reference the global market for "medicines" as well as the United States market. We also note your disclosure on [page number] that your treatment is geared towards a particular demographic, namely, adult patients with anxiety and cognitive decline typically associated with early-stage dementia, as well as those with chronic pain. Please revise your disclosure or otherwise provide additional context on why the global and domestic statistics for all medicines is relevant given your current product candidate's apparent more narrow potential indications.*

> *We note your graphic disclosure depicting the total addressable population on [page number]. Please identify the referenced "published literature," and provide a more detailed discussion of the underlying assumptions used in your calculations.*



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 50.9% of entity-background comments in 2023-2024, registering a significant increase from a 30.2% share in 2022-2023.

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.

Description of strategic direction and technological platforms took center stage this period, with the SEC requiring registrants to clarify their differentiated approaches, proprietary platforms, established leadership positions, and rapid growth. This included backing such descriptions with a comprehensive discussion of how such platform/technology/approach has developed within the firm, what concrete milestones it has achieved, and how it will support different functions to give the company a competitive edge. If there isn't enough data to back these claims, this must be clearly stated in the Summary section itself.

Similarly, description of an entity's value proposition needs to be balanced with an equally prominent disclosure of all challenges the entity faces in its overall product development plans as well as any risks and limitations that could harm the business or inhibit its strategic objectives. This includes addressing risks related to getting complex and novel products out in the market as they might involve a longer route to commercialization.

Holistically, the language of description is a critical feature in this section. Given that these disclosures are intended to provide investors with an objective depiction of an entity's operations, subjective statements and words such as "best-in-class", "first-in-class", "high quality", and "superior" must be avoided unless there's concrete evidence in support.

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 statements of belief that your Platform-driven approach to developing therapeutics will enable you to improve upon the high failure rates of late-stage clinical trials and improve your product candidates' probability of clinical success. Please balance these and other statements in your Summary by prominently highlighting that: • your Platform is unproven and clinical evidence to support your approach is preliminary and limited at this time; • there can be no guarantee that your candidates will have an increased chance of approval. Make conforming revisions throughout, including in the Business section, as appropriate.*

> *We note your response to prior comment 12. However, we do not note any revised disclosure specifying the planned timing for prospective expansions relating to your production capacity and laboratory space. Please revise or advise.*

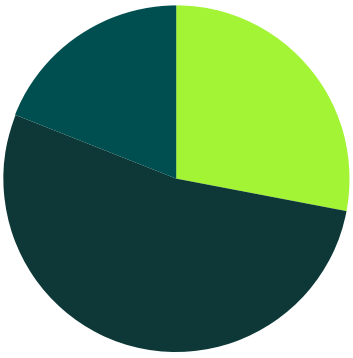
> *We note your disclosure that your team has progressed products from research to clinical trials, and ultimately to regulatory approval and commercialization. Please balance this disclosure with the statement on [page number] that novel products, such as yours, can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.*

> *We note your disclosure that you aim to bring transformational change to this field by applying your proprietary technology. Please revise to disclose what technology you have developed versus what technology you have in-licensed.*

> *Revise your Overview discussion to clarify that you have no approved products and that all of your product candidates are preclinical.*

MANAGEMENT'S DISCUSSION AND ANALYSIS (MD&A)

FIGURE 8: Number of Comments for Form S-1
By Management's Discussion and Analysis Subcategory



2022-2023

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

36 Total Comments

2023-2024

35%	Critical Accounting Policies
55%	Liquidity and Capital Resources
10%	Results from Operations

48 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.

Item 303 has undergone significant changes under the SEC's modernization drive to become more company- and investor-friendly. The objective has been 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 8.9% of total Form S-1 comments in 2023–2024—a slight increase from a share of 7.4% in 2022–2023.

Within this, a majority of comments were centered around liquidity and capital resources, followed by a considerable amount of focus on critical accounting policies. Comments on operational results were relatively less in number. This breakdown was observed in the prior period as well.

LIQUIDITY AND CAPITAL RESOURCES

Comments in this topic made up 54.2% of MD&A comments in 2023–2024, a further increase from a share of 52.8% 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 the obligation type and the relevant period for related cash requirements. This included discussing any material change in cash and equivalents reported in financial statements.

The major portion of SEC scrutiny this period, as that in the prior period, was centered around the following areas:

- **Implication of Registrants' Offerings.** Companies must reflect if their offerings involve the potential sale of a substantial portion of shares and discuss how such sales could impact the market price of their common stock. This includes discussing how such could potentially hinder their ability to raise capital at favorable terms. Further, where companies see the likelihood of receiving limited proceeds in their offerings from the exercise of stock warrants or stock options due to exercise and trading price disparity, they must expand their capital resources discussion to address any changes in their liquidity position, including the need to seek additional capital.
- **Revenue Projections.** Revenue projections must be duly explained and supported as they present possible changes to liquidity. Companies that appear to be missing their year-end revenue projections need to provide updated information about their financial position and further risks to business operations and liquidity in light of these circumstances.

The SEC also required some companies to expand their disclosures of net cash flow, to quantify large sums of cash and non-cash payments.

Meanwhile, some companies were also asked to clarify if they have entered into any agreements with their selling holders that provide investors the right to sell back shares to the company at a fixed price. If so, such companies must discuss the risks these agreements may pose to other holders if they are required to buy back the shares of their common stock, including the impact on cash availability.

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

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

> *In light of 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.*

> *It appears that you will miss your 2023 revenue projection. Please update your disclosure in Liquidity and Capital Resources, and elsewhere, to provide updated information about the company's financial position and further risks to the business operations and liquidity in light of these circumstances.*

CRITICAL ACCOUNTING POLICIES

Comments directed toward critical accounting policies made up 35.4% of the MD&A mix in 2023–2024, registering a moderate increase from a share of 27.8% in 2022-2023.

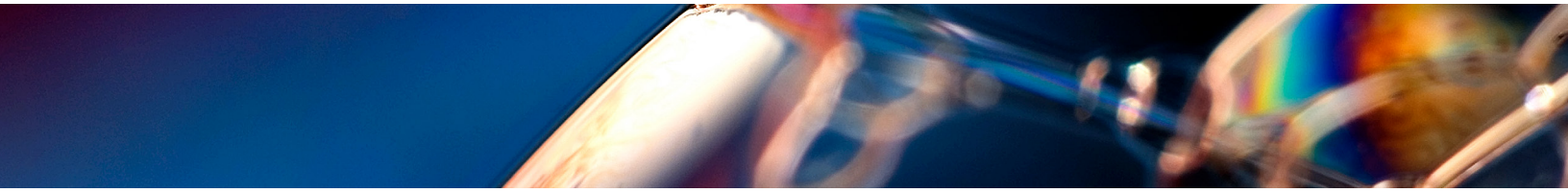
The nature of comments was largely the same. The SEC placed emphasis on registrants to outline their methods, assumptions, and estimates underlying critical accounting measurements and how changing them would impact financial results.

This included providing the accounting treatment for the following:

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

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 to 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.



Sample Comments

> *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 IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances. Please discuss with the staff how to submit your response.*

> *Please revise to disclose your revenue recognition policy within the audited financial statements including your policy for contract modifications in accordance with ASC 606- 10-25-10 through 25-13, as set forth in ASC 606-10-50-1. Provide us with your comprehensive analysis for the accounting treatment applied to the [contract name] contract modification discussed on [page number], including specific references to the supporting authoritative accounting guidance. Also, revise the disclosure of your revenue recognition policies and estimates within MD&A to discuss your policy for contract modifications, focusing on the assumptions and uncertainties underlying this critical accounting estimate. Refer to SEC Release No. 33-8350.*

> *Please tell us your accounting analysis with regards to the common stock purchase warrant issued to [party name] citing supportive, authoritative accounting guidance and revise to disclose your accounting for the warrant, providing quantification as applicable.*

RESULTS FROM OPERATIONS

Comments related to operational results made up 10.4% of total MD&A comments this period, a further decline from a low of 19.4% in 2022-2023.

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.

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.

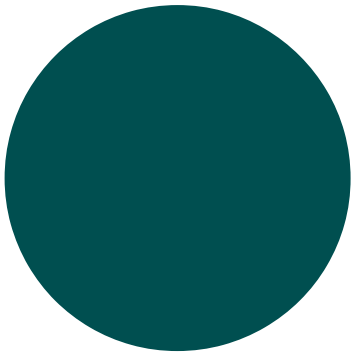
Sample Comments

> *For each of the periods presented, please quantify each factor identified for the increase/decrease in each of your expense line items. As part of your response, please address the following: • Please revise your results of operations to provide a quantified breakdown of your research and development expense by nature or type of expense, and discuss each component, as applicable. • Disclose how much of your [dollar amount] in stock compensation expense was applicable to general and administrative expense and research and development expense.*

> *Please revise your discussion to provide more insight and analysis into your period over period changes in revenue, including significant events that impacted the timing of revenue recognition. For example, discuss the concentration of sales activity that occurred in [month] and the reason for it, as referred to in prior comment 29, the launch of new products [product names] including relevant launch dates, etc.*

RESALE OFFERING

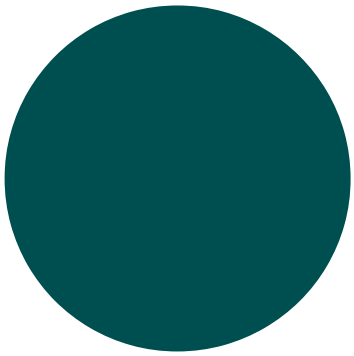
FIGURE 9: Number of Comments for Form S-1
By Resale Offering Subcategory



2022-2023

100% Critical Accounting Policies

54 Total Comments



2023-2024

100% Critical Accounting Policies

62 Total Comments

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.

2022-2023 saw a sudden influx of comments related to resale offerings and this trend has continued this period as well. Comments related to resale offerings made up 11.4% of Form S-1 comments in 2023-2024, staying in line with a 11.1% share from the prior 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. This includes describing the impact on liquidity and the ability of the company to fund its operations.
- Outline differences in the current securities trading price and the price sponsors or private investors paid 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, their eligibility for resale, and all offering terms.

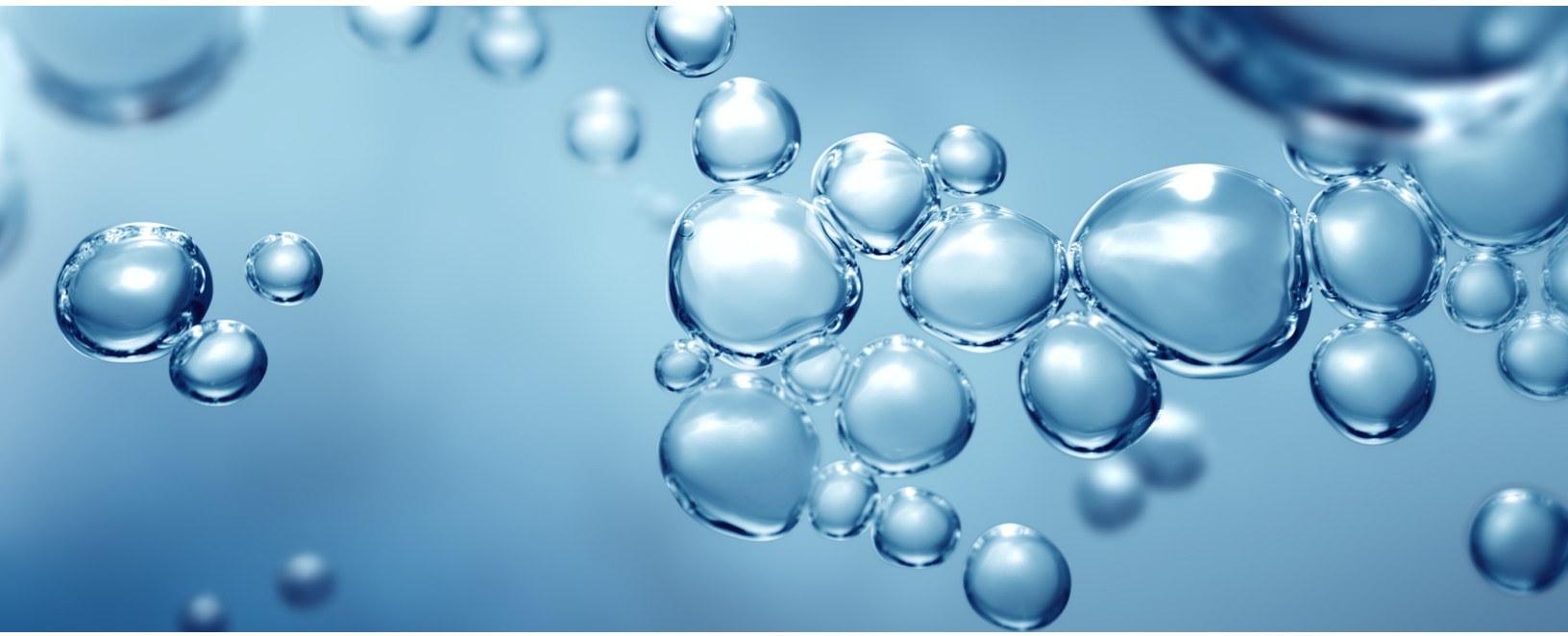
Clarity, consistency, and comprehensiveness are also essential for disclosures surrounding resale offerings. Companies need to provide complete disclosure on not just the offering itself, but also all its underlying implications, including its effect on share price, liquidity, and all other areas of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

Sample Comments

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

> *We note the significant number of redemptions of your common stock in connection with your business combination and that the shares being registered for resale will constitute a considerable percentage of your public float. We also note that some of the shares being registered for resale were purchased by the selling securityholders for prices considerably below the current market price of the common stock. Highlight the significant negative impact sales of shares on this registration statement could have on the public trading price of your common stock.*

> *Highlight any differences in the current trading price, the prices that the Sponsor, private placement investors, PIPE investors and other selling security holders 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. Please also disclose the potential profit the selling securityholders will earn based on the current trading price. Lastly, please include appropriate risk factor disclosure.*



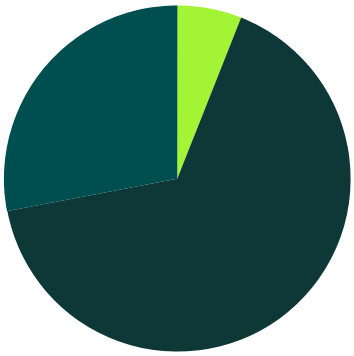
RISK DISCLOSURES

FIGURE 10: Number of Comments for Form S-1
By Risk Disclosures Subcategory

2022-2023

2%	Going Concern
63%	Risk Factors
35%	Updated Disclosures

41 Total Comments



2023-2024

6%	Going Concern
66%	Risk Factors
28%	Updated Disclosures

32 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 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 to 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.

This period, comments related to risk-based disclosures made up 5.9% of total Form S-1 comments, which is down from a share of 8.4% in 2022–2023. Despite this numerical decline, this category continued to maintain its rigor of focus as that seen in prior periods, spanning over a wide range of areas.

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.

Many of the comments, as in the prior period, were directed to resale registrants, asking them to highlight the negative pressure potential sales of shares pursuant to the registration statement could have on the public trading price of their common stock.

There was also a considerable focus placed on related party risks this period. Companies were asked to add a risk factor disclosure concerning their related-party arrangements and discuss any conflicts of interest that may arise within their executive officers and directors due to their linkages with other firms.

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 but also update their disclosures 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

> *Consistent with your disclosure on [page number] please revise your summary risk and risk factor disclosure where appropriate to highlight that issued patents covering the composition of [candidate name], one of your lead product candidates, are due to retire in 2024 and patents covering the method of its manufacturing are due to expire in 2030.*

> *Include an additional risk factor highlighting the negative pressure potential sales of shares pursuant to this registration statement could have on the public trading price of your common stock. To illustrate this risk, disclose the purchase price of the securities being registered for resale and the percentage that these shares currently represent of the total number of shares outstanding. Also disclose, if true, that even though the current trading price is significantly below the SPAC IPO price, the private investors have an incentive to sell because they will still profit on sales because they purchased their shares at a lower price than the public investors.*

> *In light of your relationship with [party name], please consider including a risk factor discussing risk resulting from any conflicts of interest or the appearance of conflicts of interest. In this regard, we note that certain of your executive officers are also senior management within [party name].*

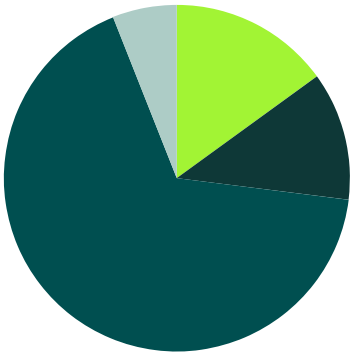
SEC REPORTING

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

2022-2023

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

56 Total Comments



2023-2024

15%	Discrepancies
12%	Filing of Exhibits and Other Material
67%	Updated Disclosures
6%	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 2023–2024, comments related to process compliance made up roughly 12% of total Form S-1 comments, which is a slight increase from a share of 11.5% in 2022–2023.

Like prior periods, registrants were asked to add to or modify disclosures to align with Regulation S-K and Regulation S-X requirements and make their statements transparent, comprehensive, and unambiguous.

This included:

- Providing all relevant exhibits
- Updating financial statements
- Adding the right number of signatures
- 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 modernization drive and regulatory updates made in the last five years are meant to facilitate simple and comprehensive disclosures. Meanwhile, technological disruption and climate disclosures have introduced additional issues critical to business reporting. The SEC is consequently designing new policies around these areas to keep up with changing market trends.

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, accounting for roughly 15.4% of process compliance comments in 2023–2024. This is an increase from a share of 10.7% in the last period.

Like prior periods, companies were asked to correct numerical errors, clarify misleading product approval claims, as well as reconcile details relating to offering terms, securities, and underwriters.

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.

A majority of comments were focused upon the consistency of financial line items this period, given that certain amounts from financial statements were reflected and discussed in many sections of the statement. There were quite a few occasions when revenue and expense amounts didn't agree to their reported figures. Consequently, companies are encouraged to be cautious when extracting such information and make sure they take the line item and its associated amount directly from their financial statements.

Sample Comments

> *Here you state that the common stock in this footnote has not been given retrospective adjustment as discussed in [note number]. However, [note number] states that all references to common stock and related information contained in the consolidated financial statements and related footnotes have been retrospectively adjusted. Please revise to be consistent.*

> *Your disclosure on [page number] indicates that you intend to avail yourselves of the extended transition period for complying with new or revised accounting standards. The cover page indicates the opposite. Please revise to address this apparent inconsistency.*

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.

Even though comments in this sub-area saw a dip this period, comprising 12.3% of the process compliance mix as opposed to a share of 33.9% in 2022-2023, the criticality of disclosures remains in-tact.

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
- Expert opinions and consents

Companies were asked to file all relevant documents as exhibits, and 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 the 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.

Concurrently, companies must also ensure compliance with Exchange Act Rule 12b-12(d), which states "if any exhibit or other papers or document filed with a statement or report is in a foreign language, it shall be accompanied by a summary, version or translation in the English language."

A summary of an exhibit must include a summary of each provision of the exhibit, just as an English language version or translation would include each provision.

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

> *Please file [exhibit number] to include filing fees and associated information. Refer to SEC Release No. 33-10997 for additional guidance.*

> *Please file the form of warrants, the form of pre-funded warrants, and the agreement with your placement agent for this offering as exhibits to your registration statement.*

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 66.2% of process compliance comments this period, registering an increase from a share of 46.4% in 2022-2023.

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
- Update the prospectus summary and relevant sections of the document to account for potential bankruptcy concerns and their implications
- Update the status of product candidates, including their development stage, regulatory approval pathway, and patent applications
- Update disclosures on the impact of new tax laws and other legislation
- 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.

Some companies were also asked to revise and update the language of certain statements, providing more certainty for events that have occurred and contingencies, if any, that have been met.

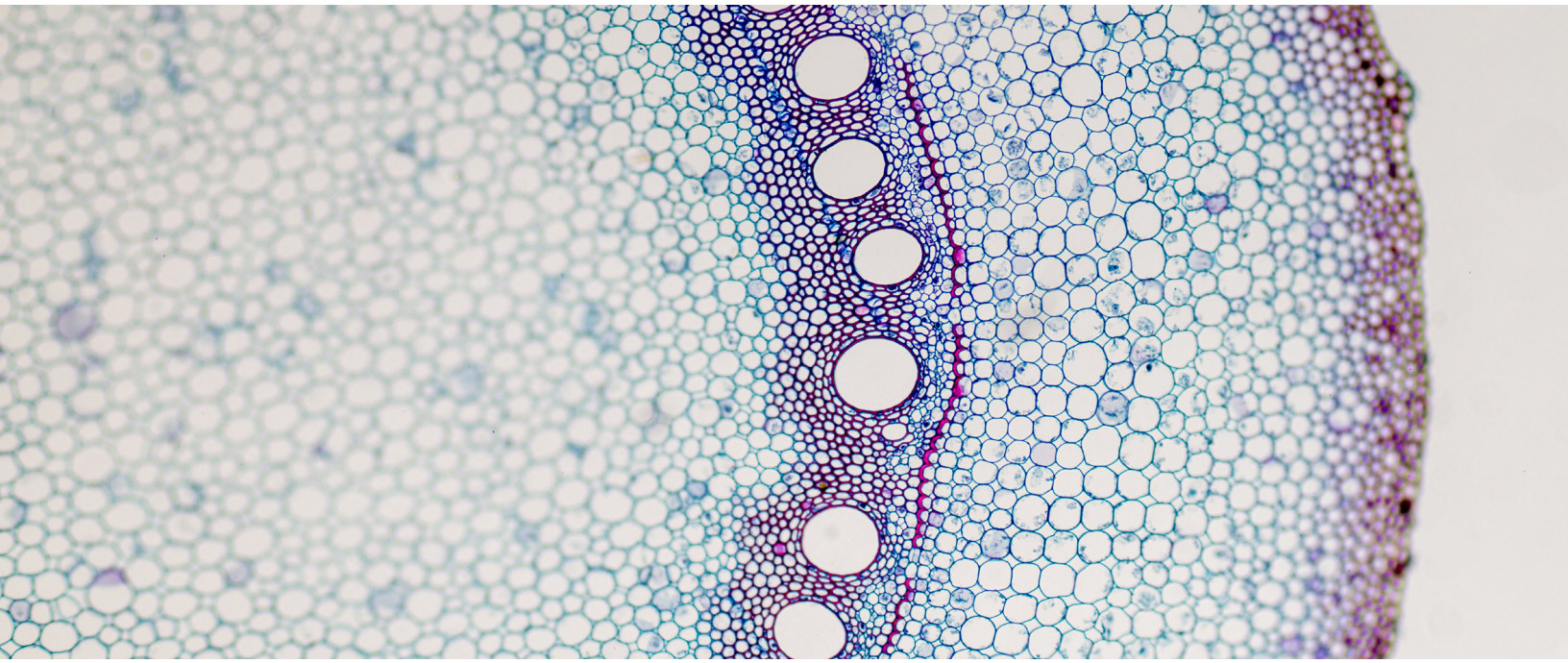
Because this section deals with information provided throughout the statement, SEC scrutiny is expected to continue. The most important consideration for registrants is keeping information as clear and up to date as possible to prevent recurring revisions.

Sample Comments

> *We note that your forum selection provision identifies the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation, including any "derivative action." Please revise here and your risk factor on [page number] to disclose whether this provision applies to actions arising under the Exchange Act. In that regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.*

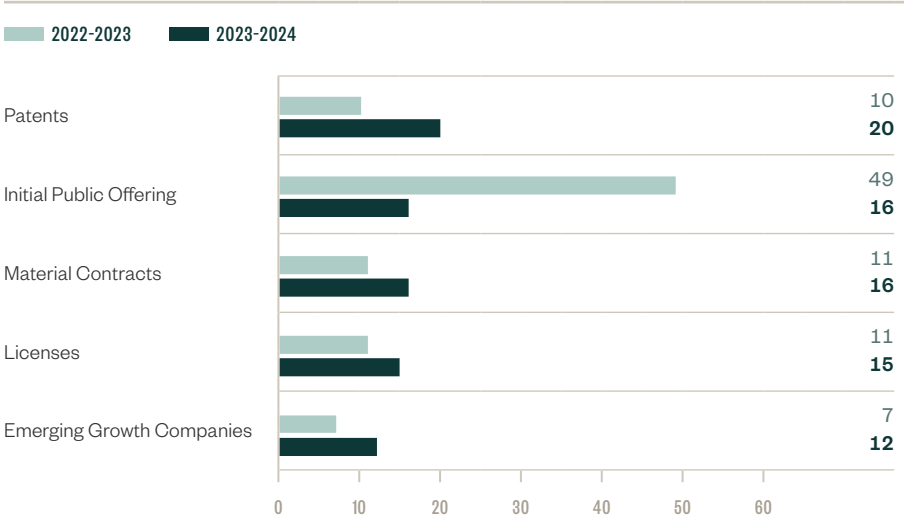
> *We note you have not filed an annual report for your most recently completed fiscal year and therefore appear to be ineligible to incorporate by reference on Form S-1. Please revise accordingly or otherwise advise. Refer to General Instruction VII.C. of Form S-1.*

> *With respect to [footnote number], the URL appears to be inactive. Please revise or remove the URL.*



OTHER DISCLOSURE TOPICS

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



A wide range of other topics were covered in SEC comments directed at Form S-1 filings in 2023-2024, including comments related to the following:

- Patents
- Initial public offering
- Material contracts
- Licensing agreements
- Emerging growth companies

Together, these comprised roughly 14.6% of total Form S-1 comments.

PATENTS

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

Comments related to patents made up 3.7% of total Form S-1 comments in 2023-2024, registering an increase from a share of 2.1% in the previous period.

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

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

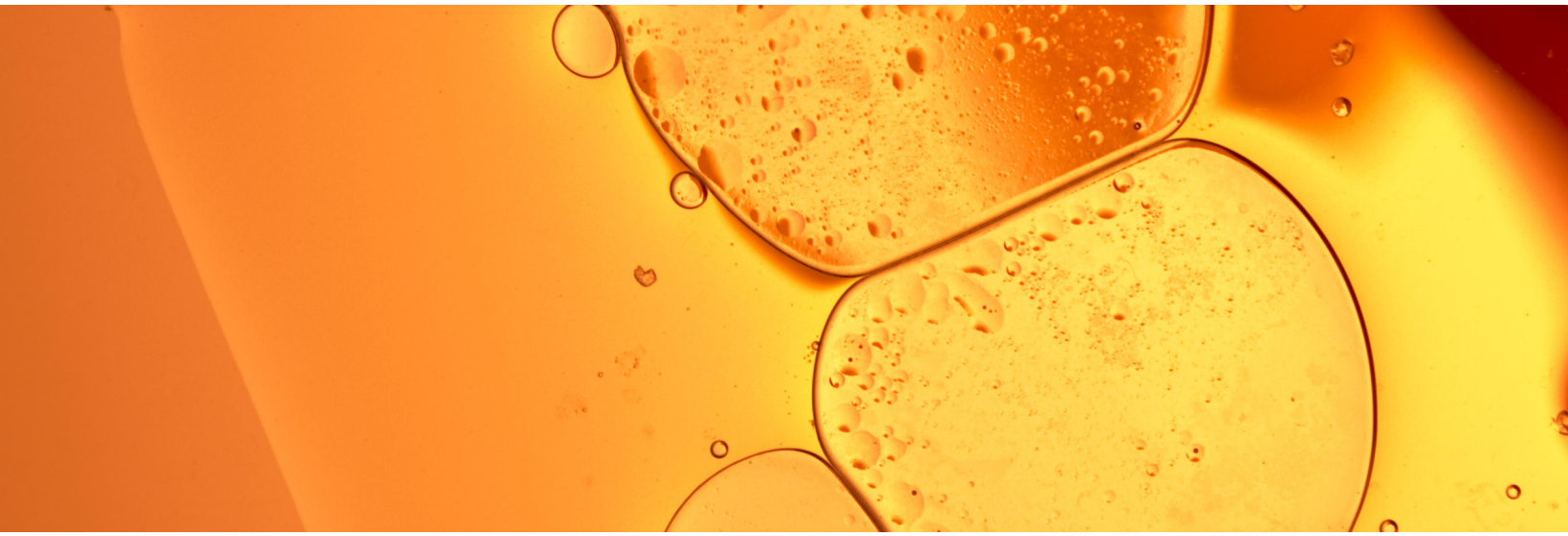
The SEC encouraged registrants to use tables to support the discussion and help prevent ambiguity on each patent and patent application's individual characteristics. Those without patent coverage were asked to disclose the risks related to the same in the Risk Factors section.

Sample Comments

> *Please revise your intellectual property disclosure starting on [page number] to disclose all foreign jurisdictions where you have pending patents for each program and disclose when you expect the patents associated with your [program name] to expire.*

> *Please revise to specify how many granted patents are covered by the license agreements and clarify the applicable jurisdictions for these patents. Clarify whether you have composition of matter patents covering your lead candidates.*

> *Please revise your disclosure to specify the nature of your pending patent applications (e.g., composition of matter, method of use or process).*



INITIAL PUBLIC OFFERING

Focus on IPO-related disclosures constituted around 3% of total Form S-1 comments this period, registering a significant decline from a share of 10.1% in 2022-2023. While this drop has been a rare occurrence, it may be attributed to the dry spell in the IPO market over the last two years that has just started to recover. Consequently, the critical nature of this category can't be overlooked, and it may generate greater limelight in the next period.

As in the past, comments in this area 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

Within offering-related disclosures, a majority of comments this period focused on market approval. If a registrant's offering is contingent upon securing listing approval in a market, then it must be stated clearly in the beginning of the statement.

Meanwhile, for use of proceeds, detail and precision remain the key takeaways. Registrants need to clearly outline how they'd use the proceeds raised from the offering to meet their specified purposes, quantifying the breakdown for each. If material amounts of other funds are necessary to accomplish the specified purposes, they need to state the related amounts and sources thereof.

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.

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

> *As you are advancing your development of [candidate name] for three different indications, please revise your use of proceeds to discuss the proceeds you intend to use to advance each of these programs and specify how far in the clinical development process you expect to reach with the proceeds of this offering.*

> *Please disclose, if accurate, that the closing of this offering is contingent upon a Nasdaq Listing, or otherwise advise. Please ensure the disclosure is consistent with your underwriting agreement.*

> *Please revise your Use Of Proceeds disclosure here and on [page number] to provide your best reasonable estimate regarding how far into development and/or the regulatory review process you expect each such program to reach using the allocated offering proceeds. If any material amounts of other funds are necessary to accomplish any specified purposes for proceeds from this offering, state the amounts and sources of other funds needed for each specified purpose. Refer to Instruction 3 to Item 504 of Regulation S-K.*

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 almost 3% of total Form S-1 comments this period, which is a slight increase from a share of 2.3% in 2022–2023.

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

- **Disclose all material provisions of agreements**, including identification of all parties involved, each party's rights and obligations, collaboration goals, nature of intellectual property or other tangible and intangible assets covered, milestone payments, royalty range or term, termination provisions, and agreement contingencies.
- **Profit sharing arrangements** that 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.

Determining 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

> *Your disclosure on [page number] states that you are working with a manufacturer to develop a time-release product which you believe is unique to the market and has potential to generate substantial revenue. Please revise your Business section to describe the material terms of this arrangement.*

> *Please revise this section to include your collaboration with [party name]. This disclosure should: describe the collaboration goal(s); identify the pipeline assets related to the collaboration, and; describe and quantify the benefits and obligations under any collaboration agreement, including quantifying payments made to date, aggregate potential milestone payments, royalty rates or applicable ranges, and term and termination provisions. If there is a written agreement underlying this collaboration, please file this agreement as an exhibit to the registration statement. Refer to Item 601(b)(10) of Regulation S-K.*

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 2.8% of total Form S-1 comments this period, which is a slight increase from a share of 2.3% in 2022–2023.

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
- Exclusivity
- Royalty term and range
- 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. Further disaggregation may also be necessary to breakdown categorical milestones.
- Trigger events or circumstances that can lead to agreement restrictions, return of unearned revenue
- Termination provisions

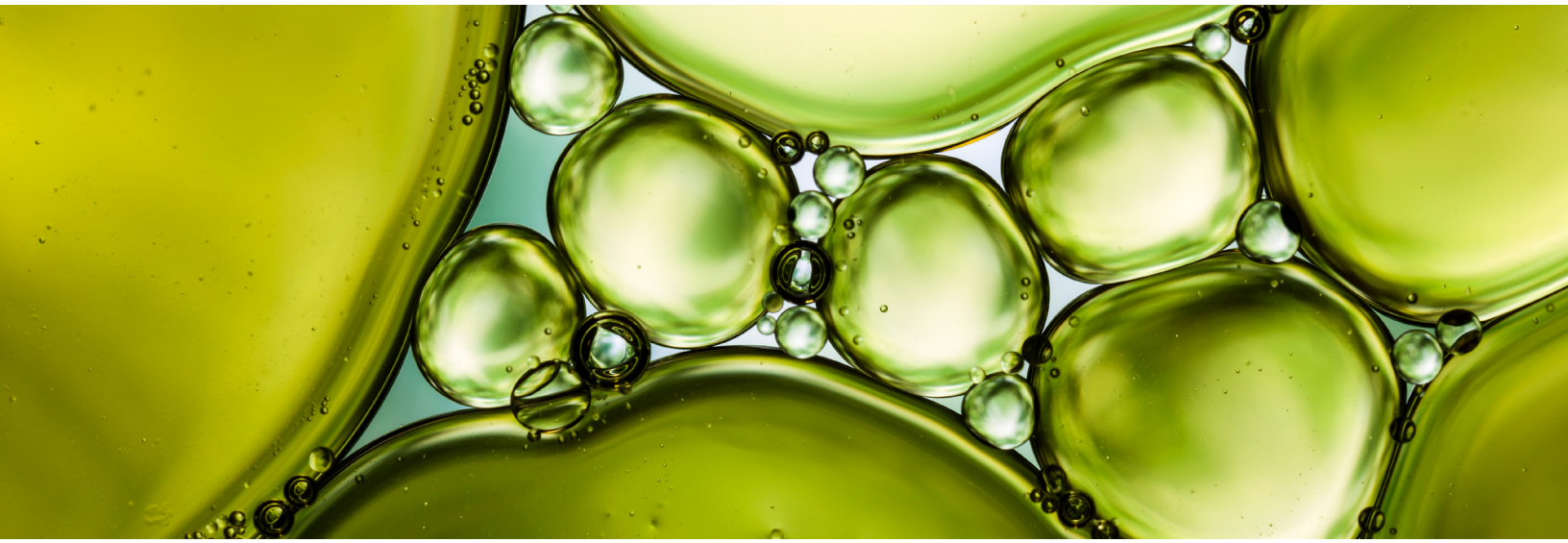
To the extent material, some registrants were also required to file the licensing agreements as an exhibit, pursuant to Item 601(b)(10) of Regulation S-K.

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 that the [license agreement] expires on a "country-by-country basis upon expiration of all royalty payment obligations for all products in such country". Please revise to provide more specificity regarding the term of the agreement as such disclosure does not provide investors with a clear understanding of the duration.*

> *Please revise your [license agreement] disclosures relating to "double-digit percentage" of milestone payments applicable to product covered by licensed patent rights on non-patented products, "low double-digit percentage" of non-royalty revenue in the event you choose to exercise your right to sublicense, and "low single-digit to a low double-digit percentage" to specify a percentage rate or range that does not exceed ten percentage points.*



EMERGING GROWTH COMPANIES

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

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

- Its total annual gross revenues are $1.235 billion or more
- It issued more than $1 billion in nonconvertible debt in the past three years
- It becomes a large-accelerated filer, as defined in Rule 12(b)-2 of the Exchange Act

Comments related to EGCs constituted 2.2% of Form S-1 comments in 2023–2024, registering a slight increase from a share of 1.4% in 2022–2023.

The SEC continued to ask registrants to provide copies of all written communications, as per Rule 405 of the Securities Act.

Sample Comments

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

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 25% of the total 727 comments analyzed in 2023-2024, which is a slight decline from a share of 30% in 2022-2023.

Topics such as process compliance, MD&A, R&D, and entity background were prime focus areas and made up 134 of the total 185 comments. This was followed by comments related to risk-based disclosures, along with a host of other comments related to internal controls, revenue recognition and various business activities. However, the number of comments within each of these categories was quite little.

Unlike its Form S-1 scrutiny, the SEC focused on companies' operational activities, financial and operating results, and procedural compliance. Emphasis on R&D, as in the prior period, was centered majorly on expense-related disclosures as opposed to pipelines and product development.

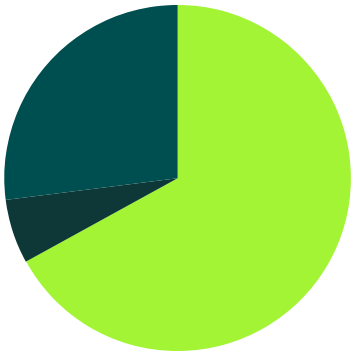
FIGURE 13: SEC Comment Categories for Forms 10-K, 10-Q, and 20-F Filings

2023-2024

25%	SEC Reporting
23%	Management's Discussion and Analysis
12%	Research and Development
12%	Entity Background
8%	Disclosures About Risk
20%	Other Comments

185 Total Comments

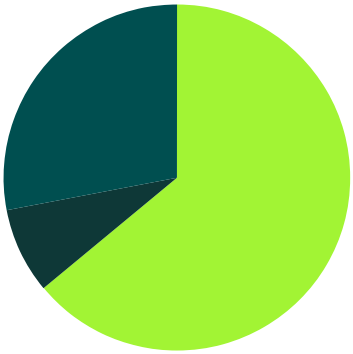
FIGURE 14: Breakdown of Forms 10-K, 10-Q and 20F Comments
By Filing Type



2022-2023

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

206 Total Comments



2023-2024

64% Form 10-K
8% Form 10-Q
28% Form 20-F

185 Total Comments

Form 10-K submissions attracted the greatest SEC scrutiny among all the three filings in 2023-2024, constituting 64% of the total 185 comments. Form 20-F filings earned 28% of the mix and Form 10-Q filings earned the remaining 8%.

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

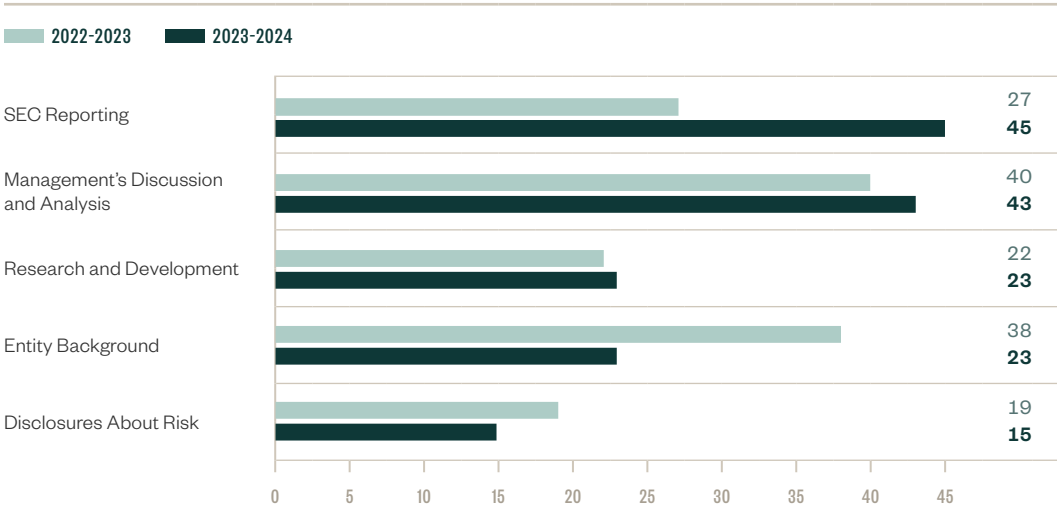
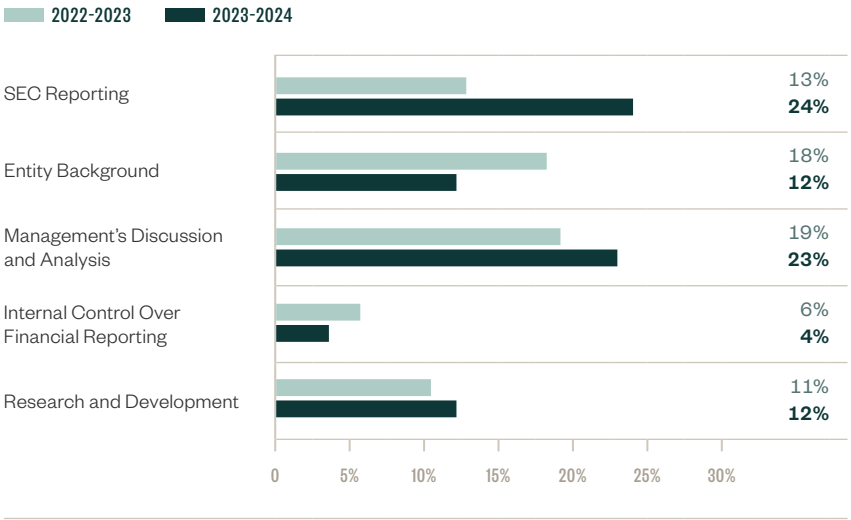


FIGURE 16: Significant Shifts in SEC Focus for Forms 10-K, 10-Q, and 20-F Filings
By Ratio of Comments



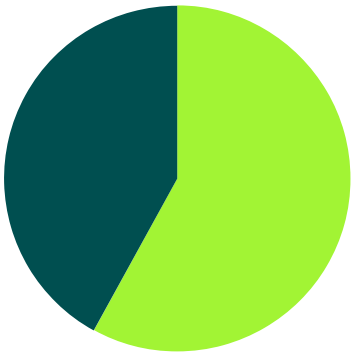
SEC scrutiny around process compliance saw a stark increase of 11.2% from the prior period. Meanwhile, comments related to MD&A and R&D increased moderately by 3.8 and 1.7% respectively.

On the other hand, focus on entity background significantly declined by 6% while that on internal control over financial reporting saw a slight decline of 2%.

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 entity background 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 AND ANALYSIS

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



2022-2023

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

40 Total Comments

2023-2024

63%	Critical Accounting Policies
2%	Liquidity and Capital Resources
35%	Results From Operations

43 Total Comments

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 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.

Consequently, focus on MD&A has been consistently staying strong and constituted 23.2% of the Forms 10-K, 10-Q and 20-F mix this period. This is a further increase from a share of 19.4% in 2022-2023.

Like prior periods, the nature of comments was 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
- Policy on receivables
- Policy on royalty-linked notes
- Policy on identification of operating and reportable segments
- Treatment of intangibles
- Inventory classification and impairment, including the meaning of specific terms and cycles
- 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.

The SEC asked filers to explain why each critical accounting estimate is subject to uncertainty and, to the extent the information is material and reasonably available, how much each estimate and/or assumption has changed over a relevant period, as well as the sensitivity of the reported amounts to the methods, assumptions and estimates underlying its calculation, as set forth in Item 303(b)(3). Accordingly, it asked companies to ensure that the disclosure of their critical accounting estimates is not merely a repetition of their significant accounting policies.

Concurrently, some companies were asked to ensure their discussion addresses only their most critical accounting policies, as opposed to substantially all accounting policies. The SEC asked such filers to revise their presentation in future filings to only include critical accounting estimates that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on the financial condition or results of operations, pursuant to Item 303(b)(3) of Regulation S-K.

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:

- Macroeconomic instability
- Inflation
- Catastrophic events like the pandemic
- Supply chain disruptions
- Generic competition

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

> *We note within your non-GAAP reconciliation that you present certain line items including but not limited to "Sale leaseback related interest expense and non-cash operating lease amortization," "Facility start-up costs / under-absorbed overhead," and "Acquisition, transaction, and other non-cash costs." Please tell us and revise future filings to explain and quantify the components of these adjustments including the nature of the charges and what they represent. Within your discussion, explain how these adjustments comply with the guidance in Item 10(e) of Regulation S-K and the Non-GAAP Financial Measures Compliance & Disclosure Interpretations. This comment also applies to the disclosures included within your aforementioned Forms 10-Q.*

> *Tell us and clarify in future filings the meaning of "normal operating cycle" as used in your accounting policy disclosure and why the criteria is appropriate for classification of inventory as long-term. Discuss the shelf-life associated with your product and explain why you believe you will be able to realize the inventory prior to the expiration of the shelf life.*

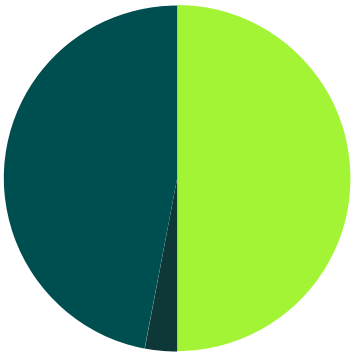
> *You state that your discussion addresses your most critical accounting policies. However, your disclosure beginning on [page number] appears to include substantially all of your accounting policies included in [note number] to the financial statements. Please confirm you will revise your presentation in future filings to only include your critical accounting estimates that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on the financial condition or results of operations pursuant to Item 303(b)(3) of Regulation S-K.*

> *In future filings please provide a more robust explanation for changes in revenues and expenses. For example, please explain the reasons for the reduction in payroll, rent and professional expenses.*

> *As a related matter, where you describe two or more factors that contributed to a material change in a financial statement line item between periods, please quantify the extent to which each factor contributed to the overall change in that line item. Refer to Item 303(b)(2) of Regulation S-K and SEC Release No. 33-8350 for guidance.*

ENTITY-RELATED INFORMATION

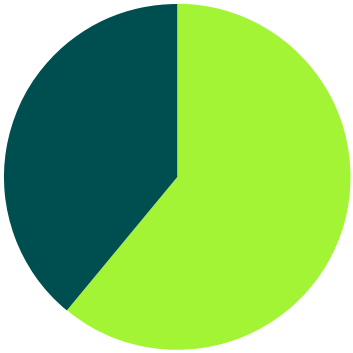
FIGURE 18: Number of Comments for Forms 10-K, 10-Q, and 20-F Filings
By Entity Related Subcategory



2022-2023

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

38 Total Comments



2023-2024

61%	Legal Structure
0%	Products and Services
39%	Regulations

23 Total Comments

Focus on entity-related information for public filers has come into the limelight over the last two periods. Even though comments in this category made up 12.4% of the Form 10-K, 10-Q, and 20-F mix this period, which is a 6% decline from 2022-2023, its importance remains in-tact.

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

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

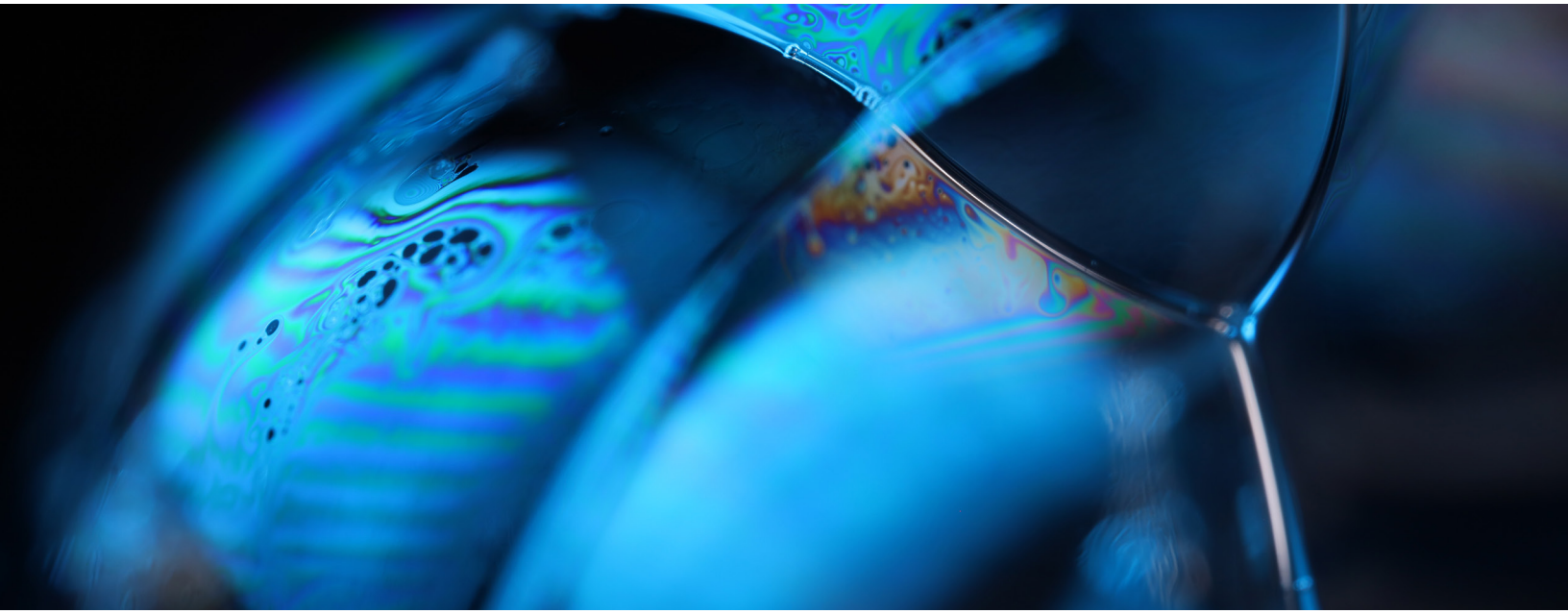
> *At the onset of Part I, Item 3 disclose prominently that you are not a Chinese operating company but a Cayman Islands holding company with operations conducted by your subsidiaries based in China and that this structure involves unique risks to investors. Provide a cross-reference to your detailed discussion of risks facing the company and the offering as a result of this structure.*

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 subsidiary conducts operations in China.

Provide a clear description of how cash is transferred through your organization. Disclose your intentions to distribute earnings. Quantify any cash flows and transfers of other assets by type that have occurred between the holding company and its subsidiaries, and direction of transfer. Quantify any dividends or distributions that subsidiaries have made to the holding company and which entity made such transfer, and their tax consequences. Similarly quantify dividends or distributions made to U.S. investors, the source, and their tax consequences. Your disclosure should make clear if no transfers, dividends, or distributions have been made to date. Describe any restrictions on foreign exchange and your ability to transfer cash between entities, across borders, and to U.S. investors. Describe any restrictions and limitations on your ability to distribute earnings from the company, including your subsidiaries, to the parent company and U.S. investors.

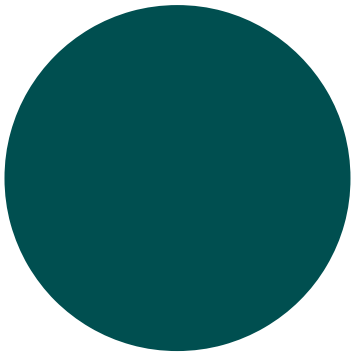
Disclose each permission or approval that you or your subsidiaries are required to obtain from Chinese authorities to operate your business and to offer securities to foreign investors. State whether you or your subsidiaries are covered by permissions requirements from the China Securities Regulatory 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.

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, as amended by the Consolidated Appropriations Act, 2023, and related regulations will affect your company.



RESEARCH AND DEVELOPMENT

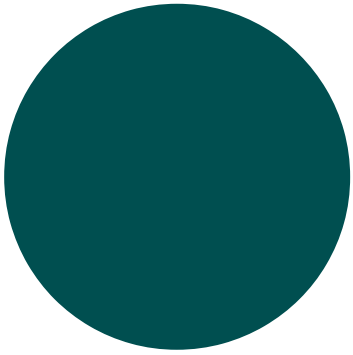
FIGURE 19: Number of Comments for Forms 10-K, 10-Q, and 20-F Filings
By R&D Related Subcategory



2022-2023

100% Expenses

22 Total Comments



2023-2024

100% Expenses

23 Total Comments

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, the SEC's scrutiny on R&D for public filers made up 12.4% of total Forms 10-K, 10-Q, and 20-F comments in 2023-2024, registering an increase from a 10.7% share last period.

Expenses continued to remain the focal point. 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 isn't 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 further add new reporting guidelines. 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.

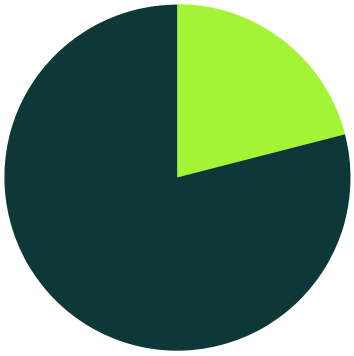
Sample Comments

> *We note that the All Other R&D category of total research and development (R&D) expense in each period presented makes up the largest component of R&D. Please revise your future disclosures, beginning with your Form 10-Q for the period ended September 30, 2023, to explain the nature of the costs included in this category and to provide a reasonably detailed explanation and quantification of the factors causing the changes therein. Consider the extent to which this line item can be further disaggregated in your tabular presentation.*

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

RISK DISCLOSURES

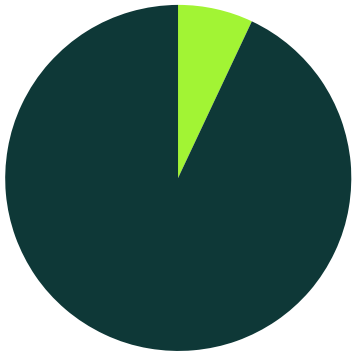
FIGURE 20: Number of Comments for Forms 10-K, 10-Q, and 20-F Filings
By Risk Disclosures Subcategory



2022-2023

21% Risk Factors
79% Updated Disclosures

19 Total Comments



2023-2024

7% Risk Factors
93% Updated Disclosures

15 Total Comments

Comments related to risk-based disclosures made up 8.1% of total Forms 10-K, 10-Q, and 20-F comments in 2023–2024, which a slight decline from a share of 9.2% in 2022–2023. Despite this fluctuation, the category continued to remain considerably prominent.

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 has been increasing entity-related comments for the past two periods, risk-based disclosures are 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 most 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 your securities 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.*

> *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 with cross-references to the more detailed discussion of these risks in the annual report. 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 the securities you are registering for sale. 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 separately 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 the securities you are registering. 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.*

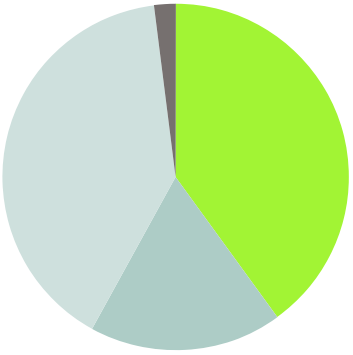
SEC REPORTING

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

2022-2023

37%	Certifications
7%	Discrepancies
15%	Filing of Exhbits and Other Material
30%	Other
0%	Disclosures Regarding Foreign Jurisdictions that Prevent Inspections
11%	Updated Disclosures

27 Total Comments



2023-2024

40%	Certifications
0%	Discrepancies
0%	Filing of Exhbits and Other Material
18%	Other
40%	Disclosures Regarding Foreign Jurisdictions that Prevent Inspections
2%	Updated Disclosures

45 Total Comments

Comments for public filers related to process compliance saw a significant rise this period, constituting 24.3% of the Forms 10-K, 10-Q, and 20-F mix as opposed to a 13.1% share in 2022-2023.

Like the prior period, many 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 refers to the design of internal reporting. Meanwhile, for Section 906 certifications, they were asked to revise and refer to the correct fiscal year.

This period also saw a significant number of comments being directed to Disclosure Regarding Foreign Jurisdictions that Prevent Inspections, pursuant to the SEC's adoption of amendments that revised Forms 20-F, 40-F, 10-K, and N-CSR to implement the disclosure and submission requirements of the HFCAA.

These amendments apply to registrants that the SEC identifies as having filed an annual report with an audit report issued by a registered public accounting firm that is located in a foreign jurisdiction and that the PCAOB is unable to inspect or investigate completely because of a position taken by an authority in that jurisdiction.

Section 3 of the HFCAA requires a CII to provide certain additional disclosure in its annual report for the year that the Commission so identifies the issuer.

Specifically, a Commission-Identified Issuer is required to disclose:

- That, during the period covered by the form, the registered public accounting firm has prepared an audit report for the issuer.
- The percentage of the shares of the issuer owned by governmental entities in the foreign jurisdiction in which the issuer is incorporated or otherwise organized.
- Whether governmental entities in the applicable foreign jurisdiction with respect to that registered public accounting firm have a controlling financial interest with respect to the issuer.
- The name of each CCP official who's a member of the board of directors of the issuer or the operating entity with respect to the issuer.
- Whether the articles of incorporation of the issuer (or equivalent organizing document) contains any charter of the CCP, including the text of any such charter.

For this, the SEC has amended Form 10-K to add Part II, Item 9C, Form 20-F to add Part II, Item 16I, Form 40-F to add paragraph B.18, and Form N-CSR to add paragraphs (i) and (j) of Item 4.

Given that these amendments aim to instill greater transparency of CII, SEC scrutiny around HFCAA disclosures is expected to stay in the limelight. Concerned public filers should carefully review the disclosure mandates and contact their industry office for more information.

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

> *We note your statement that you reviewed your register of members and public filings made by your shareholders in connection with your required submission under paragraph (a). Please supplementally describe any additional materials that were reviewed and tell us whether you relied upon any legal opinions or third party certifications such as affidavits as the basis for your submission. In your response, please provide a similarly detailed discussion of the materials reviewed and legal opinions or third party certifications relied upon in connection with the required disclosures under paragraphs (b)(2) and (3).*

> *In order to clarify the scope of your review, please supplementally describe the steps you have taken to confirm that none of the members of your board or the boards of your consolidated foreign operating entities are officials of the Chinese Communist Party. For instance, please tell us how the board members' current or prior memberships on, or affiliations with, committees of the Chinese Communist Party factored into your determination. In addition, please tell us whether you have relied upon third party certifications such as affidavits as the basis for your disclosure.*

> *With respect to your disclosure pursuant to Item 16I(b)(5), we note that you have included language that such disclosure is "to our knowledge." Please supplementally confirm without qualification, if true, that your articles and the articles of your consolidated foreign operating entities do not contain wording from any charter of the Chinese Communist Party.*

> *We note that during your fiscal year 2022 you were identified by the Commission pursuant to Section 104(i)(2)(A) of the Sarbanes-Oxley Act of 2002 (15 U.S.C.7214(i)(2)(A)) as having retained, for the preparation of the audit report on your financial statements included in the Form 10-K, a registered public accounting firm that has a branch or office that is located in a foreign jurisdiction and that the Public Company Accounting Oversight Board had determined it is unable to inspect or investigate completely because of a position taken by an authority in the foreign jurisdiction. Please provide the documentation required by Item 9C(a) of Form 10-K in the EDGAR submission form*

> *"SPDSCL-HFCAA-GOV" or tell us why you are not required to do so. Refer to the Staff Statement on the Holding Foreign Companies Accountable Act and the Consolidated Appropriations Act, 2023, available on our website.*

> *Your certifications filed as Exhibit 31.1 and 31.2 appear to include modifications from the standard language, including paragraph 4(d). In the amended filing and other future filings, please revise these certifications to include the exact language as provided in Exhibit Instruction 12 to Form 20-F.*

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)

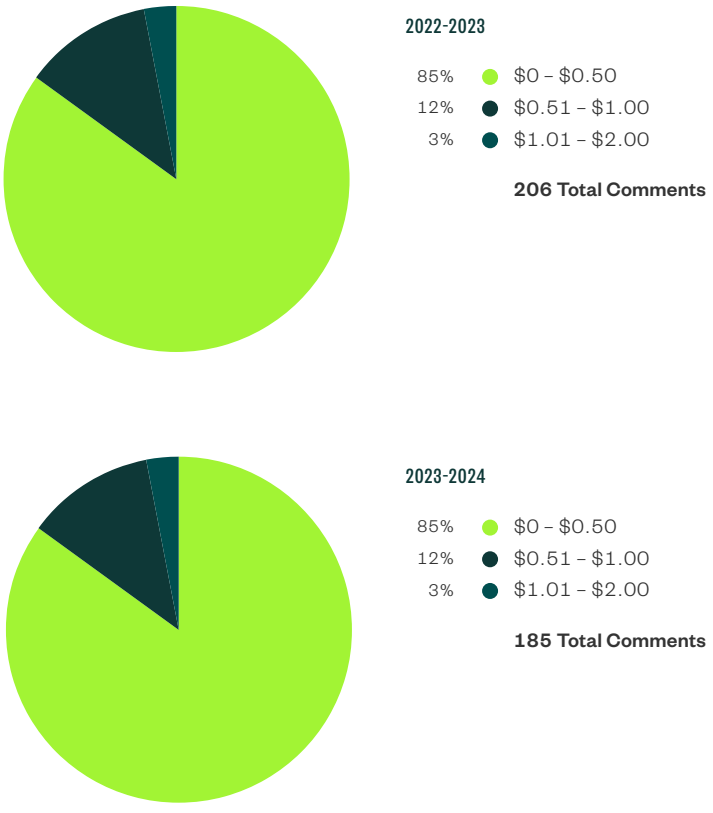
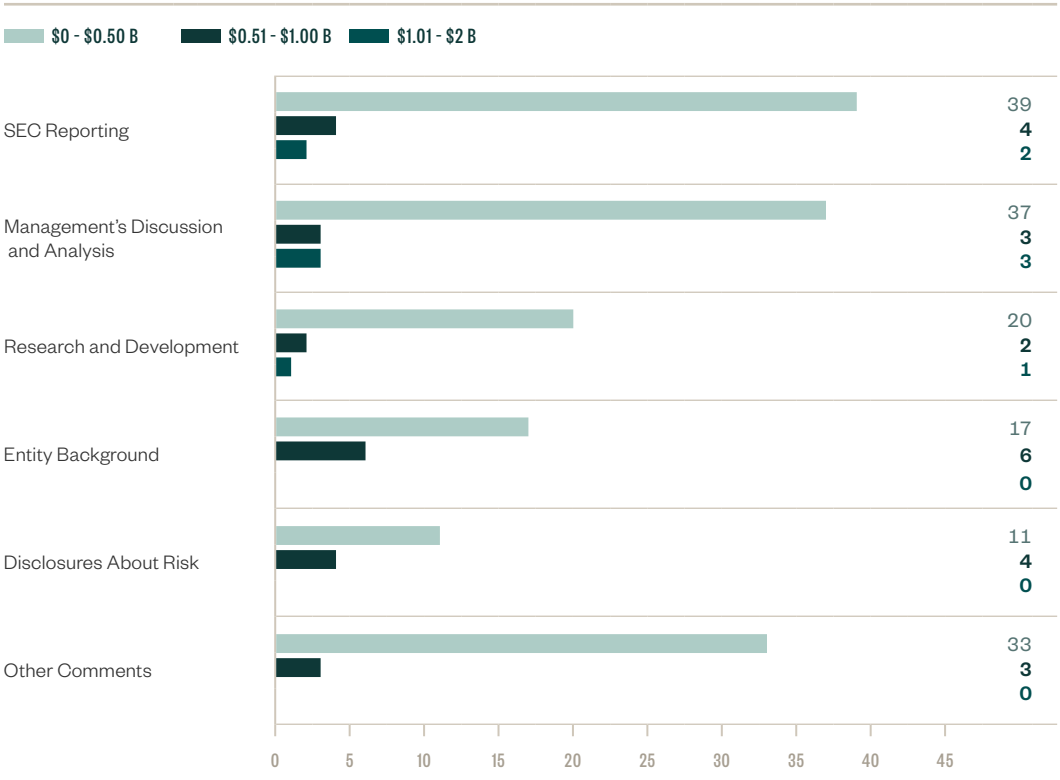


FIGURE 23: Trends in SEC Comment Categories by Market Capitalization
2023-2024 by Number of Comments



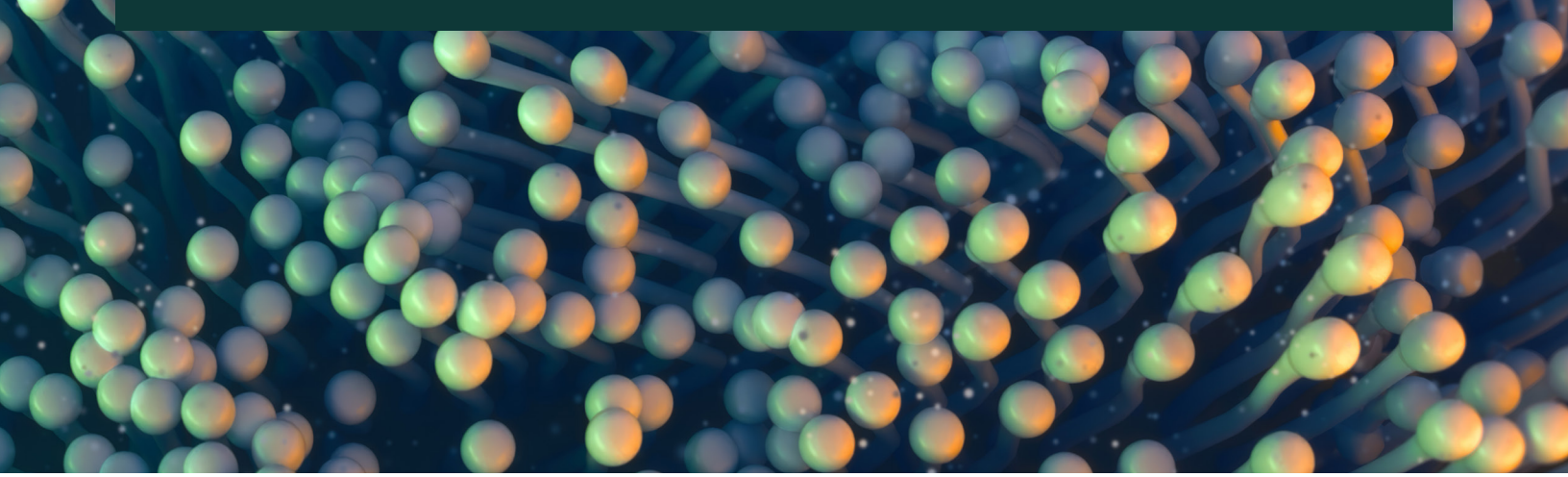
As in previous years, company size and the extent of SEC scrutiny continued to have a negative correlation; the number of comments decreased as market capitalization increased.

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.

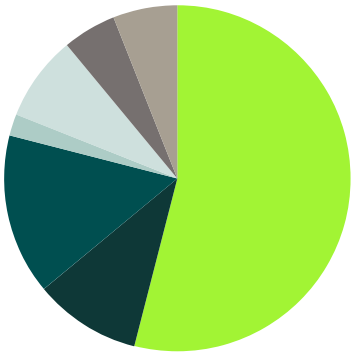
Regardless of size, building a thorough understanding of the SEC's disclosure standards will help facilitate a smoother and timely filing process for all companies.



SECTION FOUR

Subindustry Trends

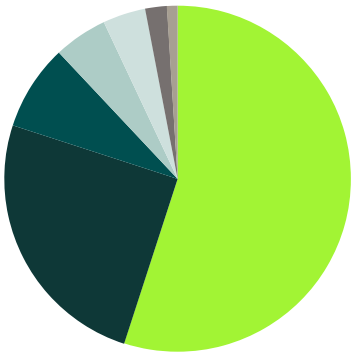
FIGURE 24: Percentage of Comments
By Subindustry



2022-2023

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

693 Total Comments



2023-2024

55%	Pharmaceutical Preparations
25%	Biological Products (No Diagnostic Substances)
8%	Surgical and Medical Instruments and Apparatus
5%	Electromedical and Electrotherapeutic Apparatus
4%	Medicinal Chemicals and Botanical Products
2%	Commercial Physical and Biological Research
1%	Other Subindustries Combined

727 Total Comments

Pharmaceutical preparations continued to attract SEC focus. Its share of total comments increased from 54.1% in 2022–2023 to 55.2% 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.

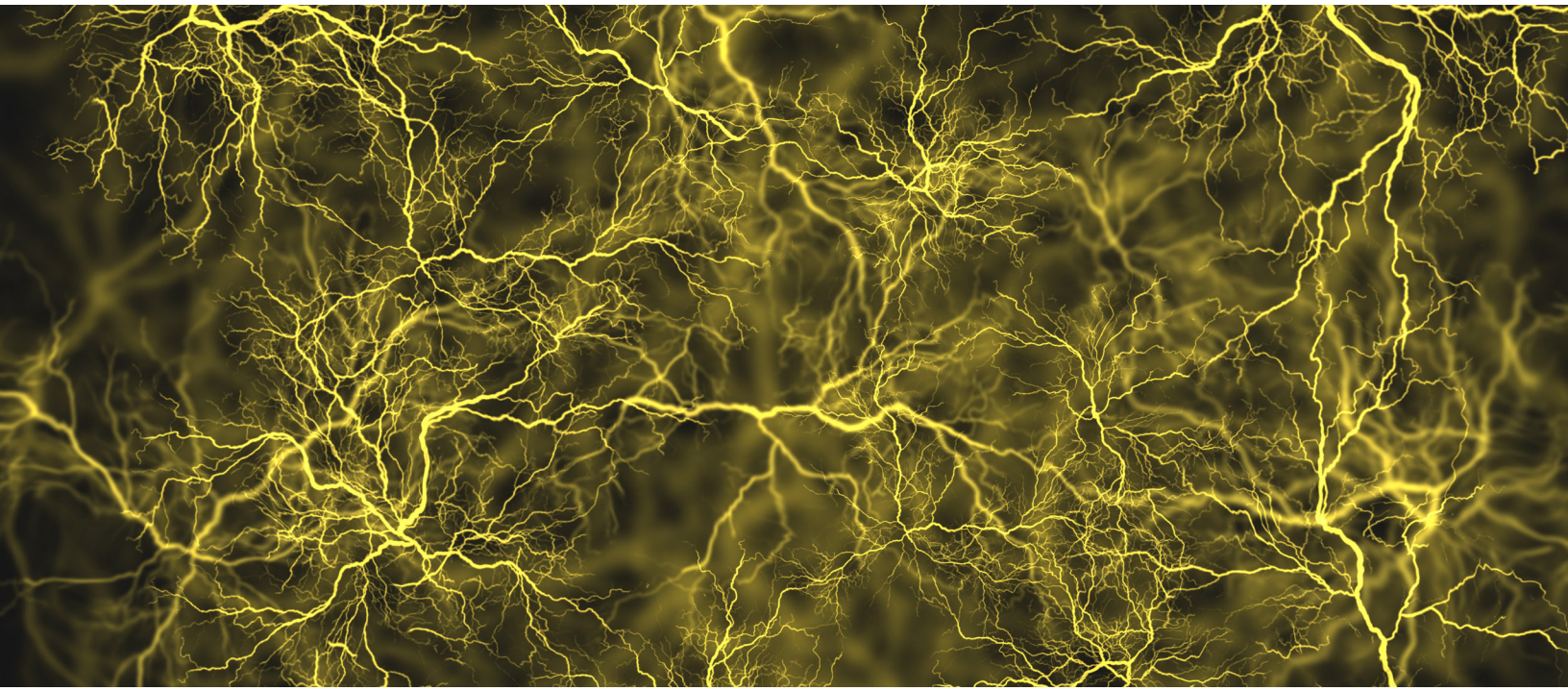
Biological products stood as the next most significant subindustry with an aggregate share of 25%, followed by surgical and medical instruments and apparatus at 8.3%.

While the ratio of comments for biological products went up by 15.2% from the previous study, surgical and medical instruments and apparatus comments dropped by 6.4%. The increase and decrease pattern between these subindustries persisted for five consecutive twelve-month periods.

Electromedical and electrotherapeutic apparatus was the fourth largest subindustry with a comment share of 4.4%. This was closely followed by comments in medicinal chemicals and botanical products with a share of 4.3%.

Commercial physical and biological research, which saw a moderate decline from the previous study, accounted for a 1.9% share in this period.

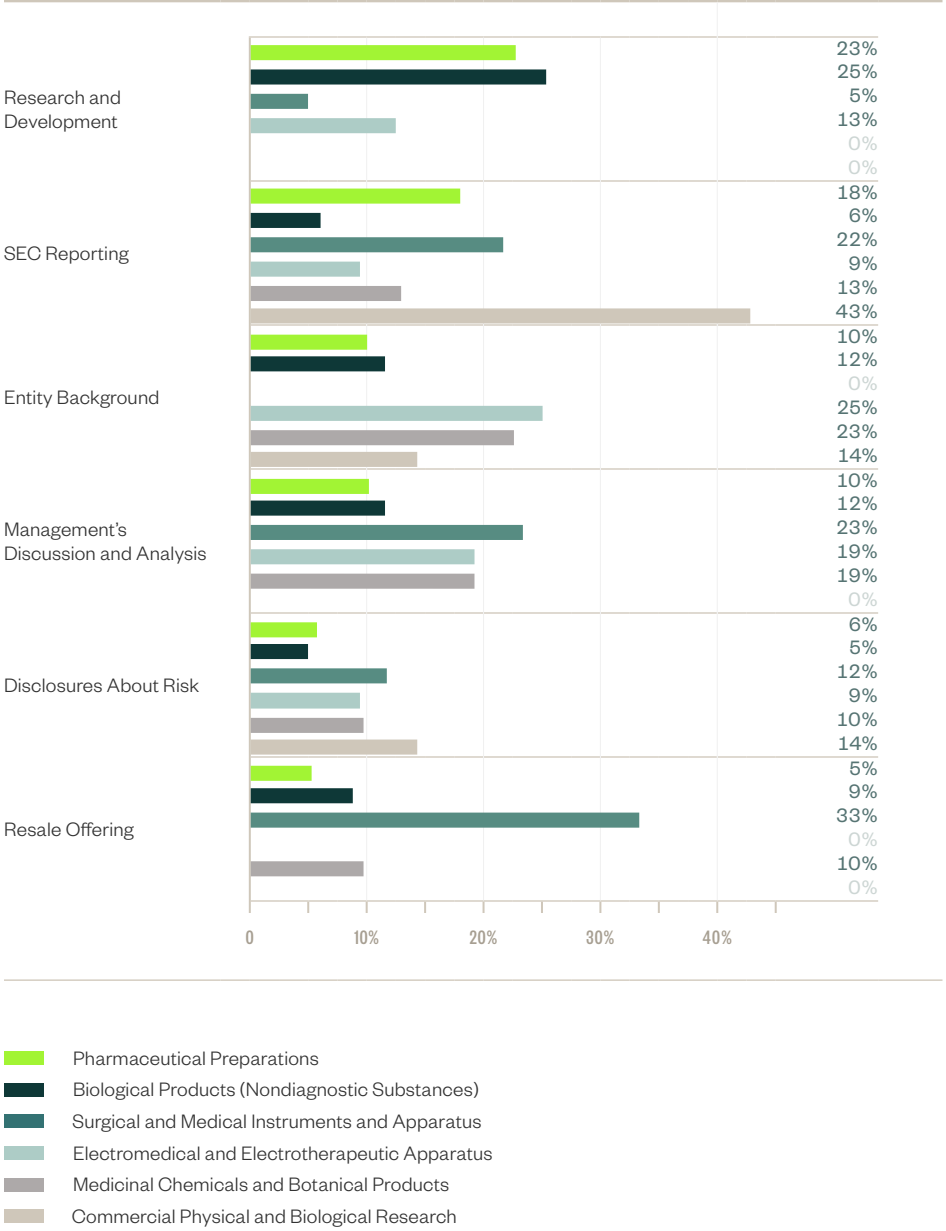
A mix of various other subindustries followed with a collective share of 1%.



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 the subindustry. 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.

On the contrary, R&D, which is always an area of focus for life sciences, has a slightly skewed subindustry spread when it comes to the number of SEC comments. Subindustries such as pharmaceutical preparations and biological products see a much higher number of comments year-over-year. This can stem from complex development pipelines, involving many clinical studies and long gestation periods. Companies are required to make expansive disclosures around such activities and any missing components can prompt comments. Consequently, comments related to R&D in the pharmaceutical preparations and biological products subindustries made up approximately 25% of the mix in each this period.

Entity-related disclosures also project a rather skewed spread. This period, comments in this category made up a large portion of SEC comments for electromedical and electrotherapeutic apparatus as well as medicinal chemicals and botanical products, generating 25% and 22.6% of the mix respectively. This stood in contrast to surgical and medical instruments and apparatus that didn't generate any comments in this area.

The last period saw an influx of comments related to resale offerings and this trend has spilled over to this period as well. However, most of these comments were tightly concentrated within the surgical and medical instruments and apparatus industry. It's important to note that this distribution isn't 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, while companies in electromedical and electrotherapeutic apparatus saw no comments in R&D last period, this category bounced back with a 12.5% share this time. Meanwhile, comments related to risk-based disclosures less than halved in proportion.

Commercial physical and biological research had more process compliance comments this period as compared to the past period, plus more scrutiny pertaining to entity-related disclosures. However, MD&A and resale offering 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 macroconditions 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

2024 has brought in a new wave of momentum for life sciences. The dry spell in the IPO market has shown signs of recovery and is expected to pick up pace in 2025. Meanwhile, product innovation and technological integration are re-engineering processes and long-term strategic goals. The FDA is encouraging breakthrough therapies while, at the same time, cautioning companies to not compromise developmental quality over speed.

Macroeconomic conditions in the marketplace also play a critical role in shaping up life sciences companies' financial strategies and performance. Geopolitical volatility can significantly affect the stability of supply chains and, accordingly, warrant greater scrutiny and transparency of a firm's geographic footprint.

These developments continue to impact capital markets, evolving the parameters that companies must demonstrate to gain investor interest and support.

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 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 2023–2024 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 to 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 2023–2024 study, when comments related to resale offerings and foreign exposure, which had recently emerged in the previous study, continued to hold the limelight. 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 operational flow.

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 firm professional.

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