MOSSADAMS

Under the Microscope

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

2020-2021

CONTENTS

INDUSTRY OVERVIEW

The life sciences industry saw an influx of initial public offering (IPO) activity in 2020 and 2021 as COVID-19 brought about unprecedented innovation and operational momentum. Product development around testing, vaccination, and treatment surged—requiring more companies to go public for funding.

PERFORMANCE RECAP

While early pandemic-driven shocks resulted in 33 life sciences companies going public in the first half of 2020, that number shot up to 65 in the second half, per Fenwick & West's IPO market review. Aggregate deal count in 2020 rose by more than 63% in comparison to 2019, excluding IPOs of special-purpose acquisition companies (SPACs). This trend spilled into 2021, with 66 deals registered in the first half of the year.

In terms of deal size, there was a lot of activity in the first half of 2020 in comparison to 2019, with over 75% of life sciences IPOs raising $100 million or more. This included two companies raising more than $1 billion each. The proliferation of offerings in the second half of the year mostly occurred in mid-sized deals, with roughly 43% of IPOs raising between $75 million and $175 million. Meanwhile, 7% raised more than $1 billion.

In 2021, over 83% of IPOs have raised $100 million or more. This trend is expected to continue as growing optimism and post-pandemic recovery catalyzes active investment in an active bull market.

Areas not driven by COVID-19—such as oncology, neurodegenerative disease therapy, and gene therapy—swept many new listings in life sciences, as well as mergers and acquisitions (M&A). Companies that paused programs to divert resources for the pandemic emergency are now resuming those programs to further expand their portfolios.

With health care in a revolutionary shift, heightened operational activity around developing multiple product lines and fast tracking otherwise-long gestation periods is bound to continue. Factors—such as less economic sensitivity, utilization of cutting-edge technology, and robust government spending and support—will keep investor interest steadfast in the sector.

KEY INDUSTRY TRENDS

A huge developmental and innovative spree in the sector has kept these areas at the forefront:

- Research
- Strategic collaborations
- Financing
- Intellectual property protection

Companies are actively broadening their product portfolios and engaging in license and supply agreements to consolidate the value chain and increase efficiency.

Ensuring a clear organizational structure and sound corporate governance has become pivotal, especially at a time when life sciences companies are racing in

time-sensitive competition. The goal to expedite the product pipeline may cause companies to potentially overlook key areas or make rushed judgments, such as:

- Management accountability and control
- Board oversight
- Decision-making
- Risk management
- Internal process frameworks

These core areas aren't only pillars of sustainability, they're also fundamental to upholding market confidence and reporting transparency. Subjects like these stand at the fulcrum of public filings, and companies are required to make comprehensive disclosure around them.

Efficient and Effective R&D

The FDA approved 53 novel drugs in 2020, including a broad spectrum of new therapies approved for patients with rare diseases, such as:

- Viral and flu infections
- Body functional diseases
- Cancer

This was the second-highest number of new drugs approved in a single year in the last 20 years, as the industry grappled with the health care crisis.

Drug manufacturers raced to submit investigational new drug and new drug applications, seeking expedited approvals to fast-track research and development (R&D) timelines. While the pandemic made efficiency the need of the hour, verifying the effectiveness of the drugs under R&D—as demonstrated through clinical trials—remained non-negotiable.

This drive to reduce experimental costs and time while increasing R&D throughput has led many businesses to adopt data-driven decisions—integrating cloud computing, machine learning, and artificial intelligence in their process nets. Digi-convergence—a term referring to the migration and convergence of traditional business processes, such as R&D or consumer profiling, to the digital realm—will continue to grow, necessitated by the drive for speed and data content.

Similar to the previous period, these dynamics were again observed in the 2020–2021 SEC comment letters, with R&D being a prime area of scrutiny. The majority of the filings under review were S-1 prospectuses, and the emphasis on objective descriptions of the following remained cardinal:

- R&D pipeline
- Process of clinical trials
- Any expedited approvals

Dual-Class Share Structures and Voting Rights

Implementation of dual-class share structures with varied voting rights has gained traction for companies that want to broaden their investor portfolio while retaining founder control. While this structure isn't as common in life sciences as it is in other industries, it's still a path used by those seeking to go public for capital accession without giving up management direction.

It's debatable how sustainable these structures are and to what extent sunset clauses will be mandatory to avoid sheltering management accountability or preventing a discrepancy between economic ownership and control.

This trend also showed up in comment letters. While SEC scrutiny on dual-class share structures didn't directly impact young and middle-market life sciences companies this period, it did attract comments for the larger S-1 applicants.

Regardless of size, any company that employs this structure had to provide clear disclosure around the following:

- Rights associated with each class of shares
- Conversion features
- Impact on overall equity structure

Apart from dual structures, a number of registrants were asked to clearly highlight the shareholders who exercised voting control and disclose whether a certain class of owners maintained a certain number of shares to control the company.

Description Versus Conclusion

Language is a core component for any company when it describes its business operations, product portfolio, and operating environment. This is particularly pertinent for players in life sciences, given the sensitivity of their products and the stringent regulatory environment.

In 2020–2021, the SEC placed considerable emphasis here when reviewing S-1 prospectuses. Aside from requesting core process compliance, the SEC required many applicants to review the language in their filings to eliminate conclusory statements about their product candidates that incorrectly signified their safety and efficacy.

Those types of determinations are solely within the authority of the FDA and comparable regulatory bodies. Companies must be able to distinguish between descriptive and conclusive terms and phrases and exercise caution when using them in the prospectus.

SEC's Modernization Amendments: A Principles-Based Approach

The SEC implemented a host of regulatory amendments in late 2021 in an attempt to modernize and improve disclosure requirements. The objective was to simplify companies' compliance efforts by emphasizing the disclosure of all information material to investors while avoiding unnecessary or duplicative disclosure.

Amendments related to description of business, legal proceedings, and risk factor disclosures—under Regulation S-K—became effective on November 9, 2020.

On November 19, 2020, the SEC announced the adoption of final amendments under Regulation S-K to streamline key areas, such as:

- Disclosure of supplementary financial information
- Requirement for management's discussion and analysis of financial condition and results of operations (MD&A)

These were published in the Federal Register on January 11, 2021, and consequently became effective from February 10, 2021.

Such refinements gel under an overall principles-based approach in lieu of a prescriptive approach, which encourages and empowers filers to decide how to best convey their material information to investors.

SEC COMMENT LETTER REPORT

RATIONALE

The objective of SEC comments is to keep market confidence intact 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 2020–2021 filings of the following forms:

S-1	10-K	10-Q	20-F

Its aim is to identify possible patterns and changes in SEC staff focus in relation to 2019–2020 filings.

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, all of which were identified by the SEC's Electronic Data Gathering, Analysis, and Retrieval System (EDGAR) Standard Industrial Classification (SIC) code.

FIGURE 1: Subindustry EDGAR SIC Codes

2833	Medical Chemicals and Botanical Products
2834	Pharmaceutical Preparations
2835	*In Vitro* and *In Vivo* Diagnostics Substances
2836	Biological Products (No Diagnostic Substance)
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 Apparatuses and Tubes and Related Irradiation Apparatuses
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 any comments related to companies with market capitalization greater than $2 billion on the dates of analysis, which were August 13 and 14, 2021.

Our analysis included comments filed on the SEC EDGAR database during the period from May 1, 2020, to April 30, 2021, which we'll refer to as 2020–2021.

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. In subsequent instances, letters from the SEC often contained comments of similar nature to those

found in the first iteration or otherwise enhanced the previous comments if not appropriately addressed.

While the period of analysis under our current and previous reports, known as 2020–2021 and 2019–2020, 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 2019–2020 to 2020–2021 exceeded the mean variance in that subset to be significant variances over the last two years.

For example, out of the 684 comments directed toward S-1 filings in 2019–2020, 144 were related to R&D, amounting to a ratio of approximately 21.1%. The same ratio increased to roughly 25.8% in 2020–2021, representing an increase of approximately 4.7%. Because this was greater than the mean variance among other topics in S-1 filings over the stipulated time period, we considered the variance in R&D-related comments toward S-1 filings to be significant.

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 comment sections.

Overall Trends

There were an aggregate 1,497 comments issued in response to Forms S-1, 10-K, 10-Q, and 20-F filings in 2020–2021, a notable 87.4% increase from 799 comments in 2019–2020.

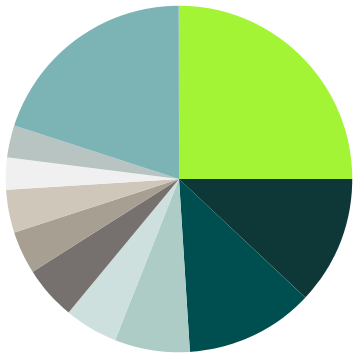
As in previous years, these comments were largely spread across key comment categories, in which those related to R&D were starkly prominent at a 25% share. The SEC continued to focus on ensuring complete disclosure when it comes to companies' clinical trials and studies, alongside requiring clarity and objectivity in developmental products and pipelines.

Process compliance was the next major category at a share of 12.2%, with most comments—as in the 2019–2020 study—requiring companies to make requisite disclosures throughout their prospectuses, including filing all material information.

This was followed by comments requiring disclosure on entity background, MD&A, and licensing agreements as well as details about the actual offering and use of proceeds.

Information around current and anticipated risks related to the business, underlying patents, material contracts, and shareholders' equity collectively constituted another significant portion of SEC scrutiny, followed by various comments targeting company-specific controls and regulatory features.

FIGURE 2: Overview of SEC Comment Categories
S-1, 10-K, 10-Q & 20-F Filings, 2020–2021 (%)



25%	Research and Development*
12%	Process Compliance**
11%	Entity Background
7%	Management's Discussion and Analysis
5%	Licenses
5%	Initial Public Offering
4%	Disclosures About Risk
4%	Patents
3%	Material Contracts
3%	Shareholders' Equity
20%	Other***

1,497 Total Comments

*R&D comments covered clinical trials and studies, FDA filings and communication, product pipeline, products and services, and other highly company-specific information.

**Comments related to process compliance tended to be more administrative and formulaic. 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.

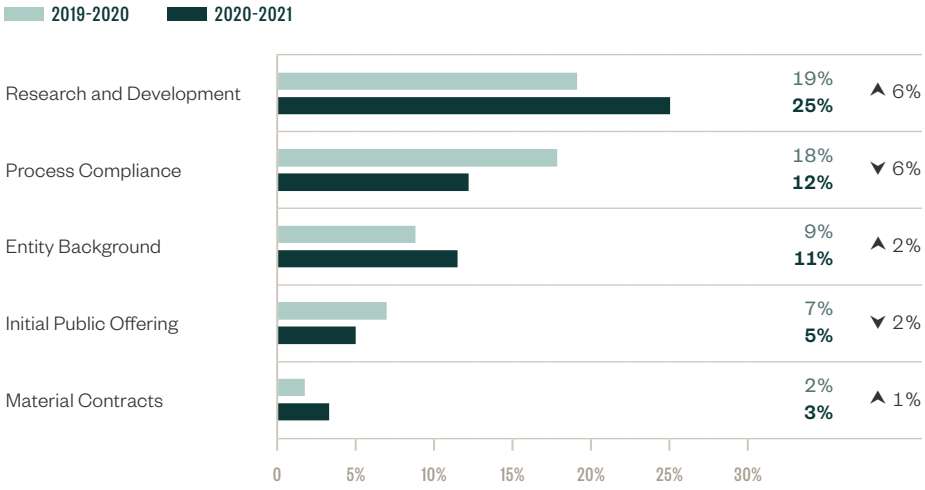
***Other recurring comments included those related to emerging growth companies, controls and procedures, proxy disclosures, revenue recognition, and language-related matters that generally pertain to the need for refining the use of certain words in a company's statement.

SIGNIFICANT SHIFTS

A number of topics saw a slight-to-significant shift in focus when compared to 2019–2020, with the positive or negative variance measured as a ratio to the total number of comments. This includes categories, such as:

- R&D
- Process compliance
- Entity background
- IPO
- Material contracts

FIGURE 3: Significant Shifts in SEC Focus for Overall Filings—By Ratio of Comments
S-1, 10-K, 10-Q & 20-F Filings, 2019–2020 & 2020–2021 (%)



Comments related to R&D significantly increased by 5.9%, while those related to entity background and material contracts rose by 2.7% and 1.5% respectively. On the other hand, comments directed toward process compliance substantially decreased by 5.6% while those on the actual offering went down by 2.1%.

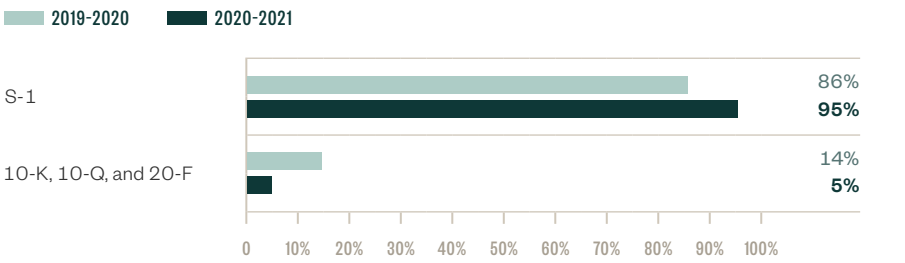
The mean variance of overall comments significantly went up from 0.9% in 2019–2020 to 1.8% this period, highlighting greater movement in comment composition. Categories—such as R&D and process compliance—were prime examples of those that saw larger magnitudes of shift, which further increased the ratio spread between the two.

COMPOSITION BY FILING TYPE

S-1 filings continued to lead in relation to SEC scrutiny, comprising most of the comments this period. Of the total 1,497 comments analyzed in the study, roughly 95%—or 1,424 comments—were directed at Form S-1. This was a substantial increase from a share of 86% in 2019–2020.

The remaining 5% of comments were directed toward Forms 10-K, 10-Q, and 20-F filings.

FIGURE 4: Ratio of Comments—By Filing Type
S-1, 10-K, 10-Q & 20-F Filings, 2019–2020 & 2020–2021



Similar to the 2019–2020 study, the nature of comment categorization varied among pre- and post-IPO companies. Comments related to R&D, process compliance, entity background, and the actual offering remained dominant for S-1 registrants while those related to licensing agreements also came into greater focus this period.

The SEC asked pre-IPO candidates to expand upon their entity structure and market disclosure, providing investors with a clearer understanding of their operational backgrounds. They were asked to do the following:

- Objectively describe products under development
- Give a concrete picture of pipelines
- Describe their utilization of proceeds from the offering

In contrast, comments for Forms 10-K, 10-Q, and 20-F filings were more focused toward disclosure related to operational performance and recurrent procedural compliance. Companies were asked to clarify information provided as part of MD&A, which included explaining differences in certain financial metrics over a previous year as well as outlining the accounting policies implemented to ascertain the same. They were also required to adhere to all internal control over financial reporting (ICFR) guidelines and file requisite certifications.

NUMBER OF COMMENTS ISSUED

The total number of SEC comments directed toward all four filings—Forms S-1, 10-K, 10-Q, and 20-F—has varied significantly over the years. While the last study of 2019–2020 saw a decrease of 35.4% in total comments from 2018-2019, that trend reversed this period. Total comments in this study equated to 1,497, which was almost double the 799 comments in 2019–2020.

This significant increase can be explained by a number of factors. First, the impact of COVID-19 spurred action in the life sciences industry, catalyzing activity in the IPO domain. Companies are readily rolling out product candidates, expanding operations, and filing to go public for funding support. As the number of these applications—or Form S-1 statements—increase, the scope for SEC review and comments also increases.

Second, Form S-1 filings generate more SEC comments on average than Forms 10-K, 10-Q, and 20-F. Applicants going public for the first time may attract more scrutiny given their limited experience in public disclosure requirements as well as the greater depth of information they must convey to investors in the initial stage.

Consequently, the majority of comment letters this period were sent in response to Form S-1 filings, and even more specifically, on the first iteration of draft registration statements (DRS). The average number of SEC comments per letter also increased, leading to a much greater sum.

As the life sciences industry continues to go on a revolutionizing shift, the number of IPOs and applications can be expected to rise. The goal for first-time filers should be to understand the filing and disclosure requirements comprehensively before submission. This will help them get the process right the first time around and cut back on the scope of further SEC questions and comments.

SECTION TWO

Trends in S-1 Filings

Form S-1 filings captured almost all of the SEC's attention in this period's study, generating over 1,424 comments. This equated to a share of 95% of the total 1,497 comments under review, substantially up from 2019–2020 when S-1 comments made up 86% of the mix.

FIGURE 5: SEC Comments Categories for S-1 Filings
S-1 Filings, 2020–2021

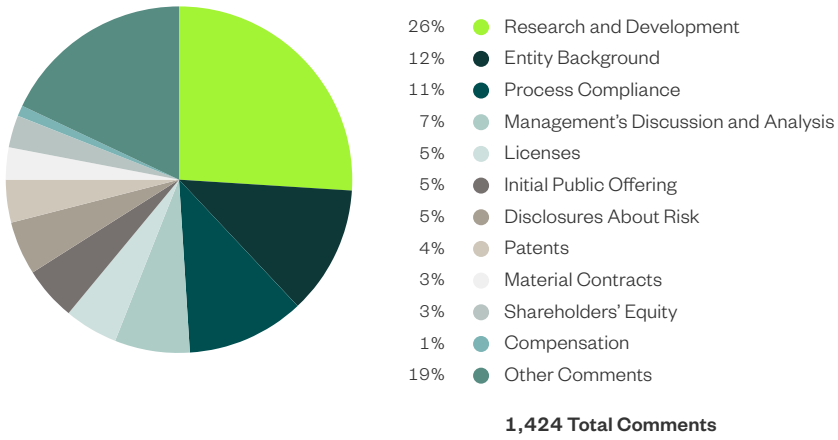
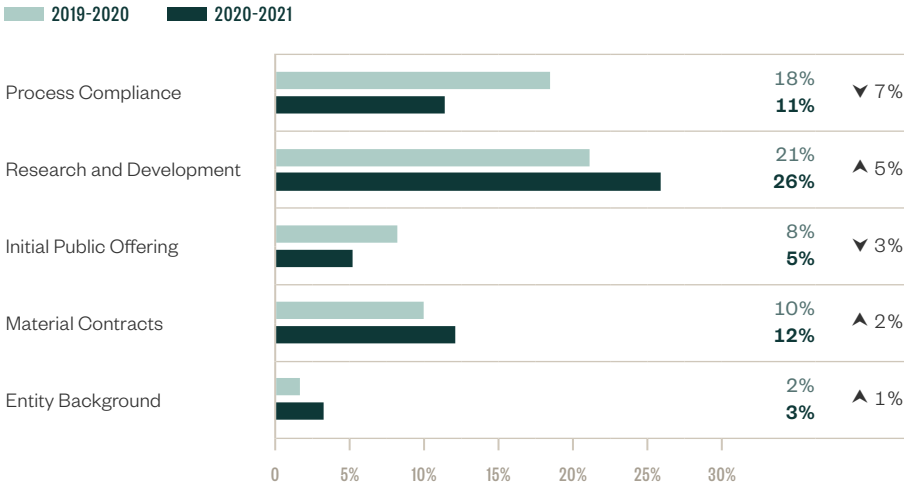


FIGURE 6: Significant Shifts in SEC Focus for S-1 Filings—By Ratio of Comments
S-1 Filings, 2019–2020 & 2020–2021



In our comparative analysis, we noted categories that made significant shifts in relation to 2019–2020. Comments related to R&D went up by 4.7% this period while those related to entity background and material contracts increased by 2.2% and 1.6% respectively.

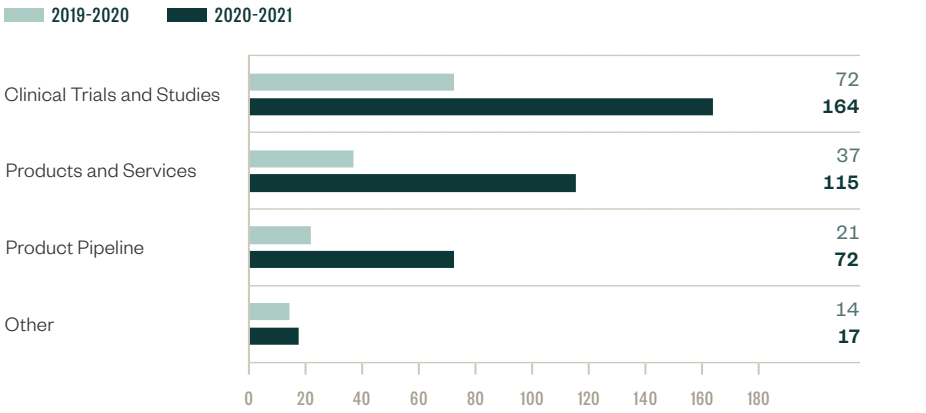
On the contrary, focus on process compliance went down by 7.1% while comments on the actual offering decreased by 3%.

The mean variance for S-1 comments increased from 1.2% in 2019–2020 to 1.9% this period, highlighting greater movement in comment composition. However, despite these shifts, certain salient topics continued to attract a large part of SEC scrutiny.

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

RESEARCH & DEVELOPMENT

FIGURE 7: Number of Comments—By Research & Development Subcategory
S-1 Filings, 2019–2020 & 2020–2021



R&D has always been the lifeline of life sciences, driving innovation and holistic health care solutions for even the most unmet needs.

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

The pandemic hasn't only put R&D in greater limelight, but it's also changed the way R&D is conducted. Many companies have revisited their developmental chains over the last period to speed up otherwise-long gestation periods and race against time for COVID-related therapies. This can involve, among other things, the following:

- Forging strategic research alliances
- Applying for fast-track approvals
- Streamlining clinical trial activities

Consequently, this also means a greater need for S-1 applicants to clearly explain how they're re-engineering their R&D chains, making sure they present an objective and reasonable timeline.

R&D has stood as a prominent category for SEC review year-over-year, and this period was no different. This was the largest area of focus, comprising over 25.8% of total S-1 comments in 2020–2021—considerably up from a 21.1% share in 2019–2020.

Within this category, comments directed toward clinical trials and studies continued to dominate the mix with a 44.6% share. This was followed by comments related to products in development and product pipelines, at shares of 31.3% and 19.6% respectively.

Apart from these core topics, a diverse range of other comments followed through, requiring greater disclosure on FDA filings and communications for developmental candidates as well as the costs undertaken to develop them.

CLINICAL TRIALS AND STUDIES

The area of clinical trials and studies continued to garner the greatest attention in R&D, encapsulating over 164 comments this period. While the proportionate share of this subcategory out of total R&D comments marginally declined from 50% in 2019–2020 to 44.6% in 2020–2021, it was still the dominant topic.

Similar to previous years, much of the SEC's focus was placed on requesting companies to make adequate disclosures for all clinical and pre-clinical studies, including the following details:

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

Registrants must state whether the primary purpose of each of their clinical trials is to evaluate safety or efficacy. In cases where they conducted different stages of trials in different countries, they should disclose whether their results from a foreign country would be accepted in the United States without any repeat testing requirements.

In terms of results, companies must disclose any serious adverse events (SAEs) observed in any of their clinical trials. To the extent that an SAE occurred, they must disclose the event and number of affected patients.

The impact of COVID-19 on current and future trials must also be clearly explained, alongside its applicable risk to the business. These issues can include the following:

- A decrease or delay in patient enrollment
- Difficulties in arranging follow-up visits
- Other program disruptions

Classification of trial stages was another key area of examination this period. Often times, registrants referenced each of their clinical trials in multiple phases throughout the prospectus—Phase 1/2 trial instead of Phase 1 and Phase 2 trials, for example—without any concrete reasoning. The SEC emphasized that Phase 1, 2, or 3 should be distinctly classified unless the company received approval to conduct multiple-stage trials.

This rule holds true for registrational trials or approvals under an accelerated pathway. Applicants should clearly describe the requirements for this approval and the studies they plan to rely upon for the same. They should also disclose, where necessary, that there can be no assurance that the FDA will permit an expedited approval process.

Comparability is another critical parameter. 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 be used for other approvals as well.

Use of external studies, such as surveys, should be duly explained in the Business section. This explanation should provide key details, such as:

- Who conducted the study
- How it was conducted
- Timeframe for test results
- What results are intended to convey

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

In summary, information sufficiency, clarity, and objectivity is key. Given the criticality of clinical trials and studies in the R&D cycle, companies must take due care to make comprehensive disclosures, remain objective, and base all statements on concrete data.

Sample Comments

> *We note your disclosure of certain pre-clinical study results throughout this section and elsewhere in your draft registration statement. Please describe additional material information about the studies, including the number of participants, the method by which the product candidates were administered, the primary and secondary endpoints, if applicable, and a discussion of any adverse events for each of your material preclinical studies to date.*

> *We note your disclosure that the COVID-19 pandemic may negatively impact [your] business, financial condition, and results of operations by decreasing or delaying the enrollment of patients in [your] clinical trials or otherwise causing interruptions or delays in [your] programs and services. Please revise to discuss in greater detail if and how your clinical trials have been affected. Please also revise any associated risk factors to specifically discuss if and how COVID-19 has actually impacted your clinical trials. In this regard, we note the last risk factors on [page reference] appear generic and do not specifically discuss if and how your clinical trials have been impacted.*

> *Please update your discussion of your Phase 1 clinical trial of [product name] to state whether any adverse events or serious adverse events occurred over the course of the trial and whether any such events were linked to treatment. To the extent that any treatment-related adverse events were observed, please describe the nature of such events.*

> *Please revise to limit the discussion of your pre-clinical results in the Summary section to a high-level discussion of your observations, as the more detailed discussion of specific results with graphics is more appropriate for the Business section. Additionally, as the FDA or other similar regulatory authorities will need to make efficacy determinations regarding any drug product, please balance disclosures relating to the desired purpose of your product candidates with equally prominent explanations that any conclusions regarding desired effects are premature as your product candidate remains pre-clinical, and as you state on [page reference], the scientific evidence is "preliminary and limited," and your novel approach "unproven."*

> *Please remove all references to "Phase 1/2" and "Phase 2/3" clinical trials throughout the prospectus and instead reference either phase 1, 2, or 3 distinctly or tell us the basis for your belief that [you] have been approved to conduct a Phase 1/2 trial and that you will be eligible to conduct Phase 2/3 trials for your product candidates and revise your disclosure as appropriate. Our concern is that the references as currently disclosed may be read to imply a shorter clinical trial process or further progress than has actually been made and may skew a potential investor's understanding of the process applicable to the company's product candidates. Please ensure your references throughout the document are consistent with your disclosure regarding Government Regulation beginning on [page reference].*

> *We note your planned reliance on the 505(b)(2) approval pathway. Please identify and describe the studies and results you intend to rely on, including the identification of the parties that performed the studies. Additionally, describe the requirements you must satisfy in order to rely on the Section 505(b)(2) pathway.*

DEVELOPMENTAL PRODUCT PIPELINE

Given long R&D gestation periods, outlining a clear timeline of products in development is pivotal. This disclosure is typically made in a product pipeline table that demonstrates—both graphically and textually—where each candidate lies upon the developmental stage.

Consequently, this topic continues to attract a considerable amount of SEC scrutiny every year. Comments directed toward the developmental pipeline made up 19.6% of total R&D comments in 2020–2021, up by a share of 14.6% in 2019–2020.

Similar to previous years, the SEC's focus was primarily on the presentation of a clear pipeline table that accurately depicted the stage of each material product candidate. Registrants were asked to add distinct columns for each distinct phase of clinical development and place appropriate-length arrows next to each program to show progress along those phases.

The scope of the table is important. Ideally, the pipeline table should be limited to only those products that are material to the company. Programs that are too early in the discovery phase should be removed or otherwise supported with adequate reasoning that warrants their inclusion.

Registrants must also identify the source of each trial phase—for example, if a specific trial was conducted by another person or party apart from the company itself, this should be clearly stated in the table.

Overall, the key takeaway is for companies to be precise, concise, and accurate in making all timeframe representations. Information presented in the table shouldn't conflict with detailed product descriptions given in other parts of the statement.

Sample Comments

> *We note that you have included in your pipeline table two programs with undisclosed targets which appear to be in the discovery phase. Given the early-stage development of these programs, please explain why each program is sufficiently material to your business to warrant inclusion in your pipeline table.*

> *Please revise the pipeline chart to include individual columns for each of the three phases of clinical development.*

> *Your pipeline table includes three separate pre-clinical phases, which gives the impression that your product candidates are farther along in the clinical process. Revise the table to eliminate the separate column for [product stage], as that stage is not sufficiently distinct.*

> *Please adjust the status bars in the pipeline graph, as appropriate, to illustrate your product candidate's current status for each indication. For example, with respect to your [indication name], we note that your phase 2 trial is currently ongoing, however, the pipeline graph appears to indicate that the phase 2 trial has been completed.*

PRODUCT-SPECIFIC INFORMATION

Apart from the diagrammatic pipeline, it's important to provide comprehensive descriptions of all products in development. 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 for registrants to clearly disclose each of these core steps in their prospectuses, including details, such as:

- The target indication being pursued for each research program
- Novel or differentiating features being explored with respect to each product candidate
- The extent of alignment between clinical trial findings and initial product goals
- Concrete reasoning for comparing candidates with existing products in the market
- Intellectual-property protection status
- Any approvals received by the FDA or other approvals needed to advance the candidate to the next phase of development
- Feasibility plans, along with any material collaborations, involved with development

Comments related to product-specific information totaled 115 this period, comprising 31.3% of the R&D mix. This was up from a share of 25.7% in 2019–2020.

Similar to the last study, making balanced disclosures lies at the fulcrum. Given the nature of this topic, SEC comments are company-specific, and there's no set standard or template for this subject. It's up to each registrant to strike the right balance in describing all positive features as well as any associated risks or issues with each product candidate.

Companies should avoid making speculative statements for developmental progression as these can suggest inaccurate conclusions. Further, any claims regarding functionality or beneficial features that have been observed should be supported with concrete evidence.

Ultimately, it's crucial to provide a holistic and objective overview to investors.

Sample Comments

> *Please revise your statement on [page reference] and elsewhere that you intend to rapidly develop and commercialize [product name]. Clinical development is a lengthy process and indications that you will be successful in developing and commercializing your product candidate in a rapid or accelerated manner are speculative.*

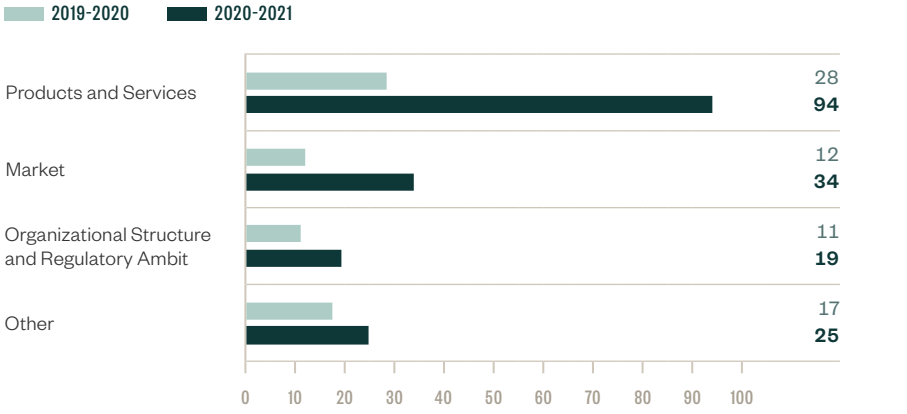
> *In your graphic and throughout your disclosure where you discuss the drawbacks of therapy approaches other than your own, clarify that your approach has not yet been approved for treatment and that the contrasts with other approaches may not be direct comparison. Please also balance your disclosure, as applicable, to discuss whether there are challenges or uncertainties with respect to developing your therapies.*

> *We note your comparisons to [drug name], an approved drug, and similar comparisons on [page reference]. We also note some similar comparisons to [drug name], another approved drug. Please tell us on what basis you believe you are able to make these comparisons given your early stage of development and the lack of any head-to-head clinical trials or, alternatively, delete these inappropriate comparisons. Please revise the prospectus throughout accordingly.*

> *Please revise your disclosure related to [product name] to balance the positive aspects of the vaccine candidate with a similarly detailed discussion of any disadvantages it may have in relation to its competitors.*

ENTITY-RELATED INFORMATION

FIGURE 8: Number of Comments—By Entity-Related Information Subcategory
S-1 Filings, 2019–2020 & 2020–2021



The need for companies to provide a thorough disclosure of their entity background and operational framework can't be overstated. This especially pertains to S-1 filers that are preparing company-specific disclosures for the first time. Registrants should set an unambiguous organizational context in the beginning of the prospectus before delving deeper into specific risk factors or business activities. This allows investors to thoroughly understand their business models and operating ecosystems in a clear and chronological manner.

The scope of disclosure for entity background largely includes details about the following:

- External environment—including competitive landscape, market potential, and size
- Existing products and services portfolio
- Organizational structure
- Regulatory ambit
- Collaborative arrangements

It further comprises disclosure of an entity's related persons, promoters, and certain control persons, pursuant to Item 404 of Regulation S-K.

There were an aggregate 172 comments pertaining to entity-related information, or entity background, in 2020–2021. These made up 12.1% of total S-1 comments, up from a share of 9.9% in 2019–2020.

Similar to the previous study, comments related to current products and services and the external environment continued to garner most of the SEC's focus, followed by comments related to the regulatory ambit. Meanwhile, comments on organizational structure increased substantially this period.

Apart from these, there were a range of other comments asking companies to further describe the following:

- Human capital measures
- Participation of certain key personnel
- Research collaboration arrangements
- Material grant-funding arrangements

Comments directed toward related parties and related-party transactions dipped in significance, comprising 3.5% of total entity background comments this period.

EXTERNAL ENVIRONMENT

Market forces are broad, independent, and ever-changing. The pandemic has increased this dynamism and volatility even further, making it critical to monitor new developments and trends.

In light of this, companies seeking to deduce operational demand and sustainability should complete the following:

- Understanding their industry and market positioning
- Narrowing down their addressable markets
- Identifying the competitive landscape

Comments directed toward the external environment—or market—constituted 19.8% of entity background comments this period, slightly up from a 17.6% share in 2019–2020.

The SEC continued to emphasize accuracy and reliability when it came to making market estimates or conducting requisite studies. Registrants were asked to validate all market size–related claims throughout the statement and provide a concrete basis for all calculations and statistics, citing any third-party sources or assumptions, as necessary.

Many companies, in their statements, provided an overall umbrella market size they were addressing with their current and upcoming products or therapies. In such cases, the SEC asked them to further break down those numbers and provide the actual proportion of markets that were directly addressable by their products or product candidates.

The takeaway for registrants is to stay as precise as possible when referring to their market opportunities, steering away from speculation.

Subjective statements such as “we’re the leading industry players” or “we have the most diversified portfolio base in the market” should be avoided unless and until the registrant has concrete reasoning or statistics to back up such claims.

Sample Comments

> *We note that your disclosure in the third paragraph on [page reference] indicates the number of patients with the enzyme deficiencies you are targeting are based on worldwide estimates. Since you currently intend to seek regulatory approval for your products in the United States and Europe, please revise to clarify your market opportunity in those targeted markets or clarify your risks in that regard.*

> *We note your disclosure regarding the size of the [disease name] market in the United States and globally. To the extent such data is available, please indicate on [page reference] your estimate of the portion of the [disease name] population that are relevant to your product candidates, for example with respect to [product name] those predisposed to increased [symptom name].*

> *We note your estimates for market opportunities and specific data points, including your statement that, “[example statement].” Please disclose in the filing the basis, including any*

> *sources and assumptions, for these statements and describe the specific risks relating to your assumptions.*

ORGANIZATIONAL STRUCTURE & REGULATORY AMBIT

Comments related to organizational structure and the overall regulatory ambit made up a considerable 11% of entity-background comments this period. While the relative share of regulation-based comments slightly decreased from 2019–2020, comments toward entity-wide structure gained significant prominence.

Providing comprehensive disclosure on the overall corporate structure is fundamental. This is basic information about the entity that helps provide the context behind all relations built and transactions conducted within the business. This becomes even more pertinent when a company goes through a corporate reorganization or adopts a specific structure or model for some of its key characteristics. Informing investors on changes within subsidiaries, percent ownership, and respective capital structure is imperative. Essentially, this should include a diagrammatic representation of the structure followed by requisite labels and concise narratives.

On the regulatory front, the trend remained similar to last period. Registrants were required to discuss relevant government regulations affecting their overall business as well as quote certain rules affecting specific products or product candidates. This included explaining how such regulations would impact product approvals going forward as well as shape their ultimate commercialization in the market.

The SEC also required companies to discuss their plans for entering foreign markets, if any, and accordingly describe the steps they'd taken to obtain the necessary regulatory and patent approvals.

With regulatory dynamism and rapid business expansion on the lines, the emphasis on providing apt disclosure on current entity structure and applicable regulatory backdrop will continue to prevail.

Sample Comments

> *We note that there are references to foreign regulators and foreign markets throughout the Risk Factors and other sections of your prospectus. We see that your IND submission for [product name] for [disease name] has been accepted in the United States and your clinical trial authorization has been accepted in the United Kingdom, but we do not see other references to applications to foreign regulators. Please revise to explain what non-US markets, if any, you plan to enter, and what steps you have taken to attain the necessary regulatory and patent approvals. Tailor the risk factors section to more closely reflect the applications you have made or are planning to make in the near term.*

> *This section of your filing discloses the future regulations that may affect the development, production, and sales of your products. Please amend this disclosure to clearly describe the regulations that apply to your current operations, including your activities related to your R&D service contracts.*

> *Please include an organization chart showing your corporate structure.*

> *We note that on [date], the Company completed a corporate reorganization. Please revise this section to clearly identify the Company's current organizational structure. Include a diagram showing the Company and its subsidiaries and indicate the respective capital structure (e.g., outstanding preferred stock and debt). We also note that on [page reference], the Company has certain entities that it considers to be variable interest entities. Please also include such entities.*

PRODUCTS AND SERVICES

Making a sound representation of existing products and services, as well as plans to develop new ones, is a core component in entity background. The Overview section of the prospectus is where registrants provide a holistic snapshot of their entity-wide operations to date, including what their current offerings and revenue streams are, if any, as well as how they're expanding the line with new candidates. This includes describing whether they designed any in-house, proprietary technology to facilitate product development and how that's helping them differentiate from competitors.

While comments here continued to constitute the majority of entity-background comments like last period, the share of comments increased from 41.2% in 2019–2020 to 54.7% in 2020–2021.

Similar to product disclosure in R&D, balanced disclosure remains pertinent here. Registrants need to objectively describe their entity operations and current products and services, which includes listing both benefits and challenges and providing the basis for those claims. They should further exercise caution in comparing their products or performance to others in the market, given that oftentimes these comparisons may not be based on head-to-head data.

Comprehensive disclosure is another key theme here. While the Summary and Overview sections are conventionally meant to stay concise, they should still contain all important information relating to existing products and services. Such disclosures include, among others:

- Characteristics of current products, their operating history, and performance metrics
- If products are still under development, the entity's extent of experience in the space—for example, whether it's developed and tested such products or if it's still in the preclinical stage
- Ownership of global commercialization rights and all intellectual property matters
- Manufacturing facilities and distributions channels set up for operations
- Dependence on key customers and suppliers, pursuant to Item 101(h)

The introductory pages of the prospectus are a gateway to the company's entire statement for going public and helps them present their story to investors. Focus here will continue to remain primary. Registrants are requested to pay great attention when it comes to drafting the contextual background, making a fair balance between precision and concision.

Sample Comments

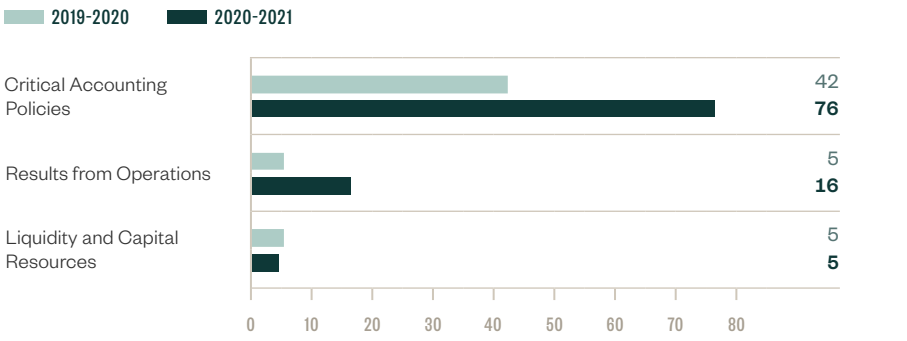
> *Please clarify here in the Overview, and throughout your registration statement where appropriate, that you are a preclinical stage company and that you currently have no marketable products or product candidates. In this regard, we note your disclosure on [page references] regarding risks associated with your business and the status of your research and development.*

> *Please ensure that the information you include in your summary is balanced. For example, we note the risk disclosure on [page references] that you have a limited operating history, have incurred significant net losses since inception, anticipate that you will continue to do so for the foreseeable future, and expect these losses to increase as you continue clinical development and seek regulatory approvals. Please provide a more detailed and prominent discussion of the most material risks you face.*

> *It is unclear why you have removed disclosure regarding the online digital platform you maintain for customers to purchase your products. Please advise or revise to disclose the website for and products currently offered on the platform and how you ensure that the distribution of your products is limited to the state of California.*

MANAGEMENT'S DISCUSSION & ANALYSIS

FIGURE 9: Number of Comments—By Management's Discussion & Analysis Subcategory
S-1 Filings, 2019–2020 & 2020–2021



The SEC's focus on MD&A comprised 6.7% of total S-1 comments in 2020–2021, slightly down from a share of 7.6% in 2019–2020.

Registrants were asked to bring to attention any extraordinary events or circumstances that varied results during the year. They were also requested to comment on the future outlook—in other words, how external forces coupled with internal company dynamics would impact results and affect certain areas of operations in the future.

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

While financial statements provide numerical metrics in relation to operational performance, it's vital to narrate the appropriate context that conveys the story behind those numbers. This is formally imputed in the MD&A section, pursuant to Item 303 of Regulation S-K, standing as a distinct section in the prospectus.

Essentially, Item 303 until now has required registrants to provide information in MD&A about the financial condition and results from operations. This has included covering aspects, such as:

- Liquidity
- Capital resources
- Operational results
- Off-balance sheet arrangements
- Contractual obligations

These were oftentimes specified in templatized formats and disclosures. However, this area has seen a shift since the SEC's final adoption of modernization amendments.

SEC'S MODERNIZATION AMENDMENTS–STREAMLINING MD&A

Holistically, the SEC's latest amendments have focused on three areas of Regulation S-K:

- Item 301, pertaining to the disclosure of selected financial data, has effectively been eliminated.
- Item 302—on supplementary financial information—has been streamlined under the principles-based approach.
- Item 303—on MD&A—has also been streamlined.

For Item 303, the amendments specifically clarify the overarching objective of MD&A under Item 303(a). It requires disclosure from management's perspective of material information, including material events and uncertainties as well as material financial and statistical data.

This means disclosure of material facts and inferences is still very much mandatory. The purpose of these amendments is to open up the reporting canvas to companies, letting them decide what information is specifically material to them and requiring disclosure and how best to disclose it.

These amendments became effective February 10, 2021.

KEY AMENDMENT CHANGES*

Liquidity and Capital Resources	Registrants must discuss their short- and long-term material cash requirements from known contractual and other obligations, not limited to commitments for capital expenditures. They must specify the anticipated source of funds needed to satisfy these cash requirements as well as the general purpose of the requirements. Registrants must discuss any known trends or demands, commitments, events, or uncertainties that are **reasonably likely** to materially impact its liquidity in any way.
Results of Operations	Registrants should describe unusual or infrequent events or transactions or significant economic changes that have materially affected their reported income from continuing operations. They must describe known trends or uncertainties that have had, or are reasonably likely to have, a material impact on net sales, revenues, or income from continuing operations. They must also describe any known events that are reasonably likely to materially change the relationship between costs and revenue. Mandatory discussion of inflation and price changes are eliminated. Registrants must only discuss these matters if they're part of a known trend or uncertainty that has had, or reasonably likely to have, a material impact on results from continuing operations.
Critical Accounting Policies	Registrants need to explicitly disclose critical accounting estimates. This includes explaining why each critical accounting estimate is subject to uncertainty, how much each estimate changed during the period, and sensitivity of reported amounts.
Others	Current prescriptive disclosure requirements for off-balance sheet arrangements are replaced with a principles-based instruction. Registrants can integrate disclosures of off-balance sheet arrangements within broader MD&A disclosures. Registrants are no longer required to provide a contractual obligations table. Greater flexibility has been allowed for interim-periods comparison. Registrants can compare their most recently completed quarter to either the corresponding quarter of the prior year or to the immediately preceding quarter.

*For details, refer to our Alert published in January 2021.

CRITICAL ACCOUNTING POLICIES

The topic of critical accounting policies continues to attract most of the SEC's attention year-over-year, making up 79.2% of total MD&A comments in 2020–2021.

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

Critical accounting estimates are estimates made in accordance with US generally accepted accounting principles (GAAP) that involve a high degree of estimation and uncertainty. Such estimates can reasonably likely impact the registrant's financial condition or results of operations in a material way. Consequently, disclosure becomes pertinent.

The SEC continued to ask registrants to provide comprehensive reasoning underlying all critical accounting estimates as well as to cite the accounting guidance relied upon. This included the following:

- Methodology behind fair value determination
- Measurement of different kinds of liabilities
- Share pricing
- Arm's-length transactions
- Line-item calculations
- Capitalization of costs
- Accounting treatment of different types of collaborative agreements

Companies were also required to explain their adoption of key accounting policies—especially on recent pronouncements, such as Financial Accounting Standards Board (FASB) Accounting Standards Codification® (ASC) Topic 606, *Revenue from Contracts with Customers*.

Removal of non-GAAP measures was also sought pursuant to Item 10(e) of Regulation S-K.

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

With the new amendments, critical accounting estimates will continue to remain an area of focus. The key for registrants will be to make explicit disclosures that, while preventing repetitiveness, promote meaningful analysis of measurement, risks, and uncertainties.

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 including stock compensation and beneficial conversion features.*

> *Please disclose your accounting policy for cash equivalents. Refer to ASC 230-10-50-1.*

> *In addition to the variable consideration mentioned, please tell us and disclose the material judgments, assumptions, and uncertainties associated with recognizing your revenue and the factors subject to estimation and variability. For factors that are variable, disclose those most subject to change and the related sensitivity to change,*

> *along with the factors that cause changes. Refer to Section V of Release No. 33-8350, Interpretation: Commission Guidance Regarding Management's Discussion and Analysis of Financial Condition and Results of Operations, available on our public website.*

RESULTS FROM OPERATIONS

Comments related to operational results comprised 16.7% of MD&A comments in 2020–2021, up from a share of 9.6% in 2019–2020.

Similar to last period, registrants were asked to provide a narrative disclosure outlining significant changes in revenue and expenses, which included identifying all company-driven factors and market forces that caused those changes. They were also asked to substantiate certain performance claims—especially as they related to the future of the business—and address key operational metrics.

Under the amendments, registrants were asked to explain the existence of any trends, events, or uncertainties that were reasonably likely to impact future results of operations or financial position.

With the impact of COVID-19, a discussion of these events and uncertainties becomes even critical.

Sample Comments

> *A [specific press release], which lists the company as its source includes many statements from you and your CEO relating to positive expectations concerning your margins, run-rate, cash flow, and other aspects of [company name] results of operations in the near term and in future periods. However, none of these forecasts or related expectations are discussed in the amended prospectus or the Form 10-Q. Please advise what consideration you've given to including this information in the prospectus insofar as it appears to reflect your current views regarding your business. Also, please provide in your response letter appropriate substantiation for each of the statements.*

> *We see that [amount] of the increase in research and development expenses related to [product name] and your other preclinical programs due to the completion of your [program name] and the submission of your investigational new drug application for [product name]. Please revise to provide a more detailed discussion of research and development expenses related to your product candidates, including a discussion of the nature of expenses incurred and the existence of any trends, events or uncertainties that are reasonably likely to impact future results of operations or financial position. See Item 303(a)(3) of Regulation S-K for further guidance.*

> *Please revise to discuss the effects, if any, that COVID-19 has had on your business, including what management expects its future impact will be, how management is responding to evolving events, and how it's planning for COVID-19–related uncertainties going forward. For guidance, see CF Disclosure Guidance: Topics No. 9 and 9A.*

LIQUIDITY AND CAPITAL RESOURCES

Comments related to liquidity and capital resources further declined this period, making up 4.2% of MD&A comments from a 9.6% share last period.

Registrants were asked to disclose their short- and long-term obligations and highlight their impact on liquidity as well as discuss possibilities of change and uncertainty.

It's worth noting that a change in the number of comments for a particular category shouldn't be construed as a reflection of its importance. A declining number of comments may merely suggest companies are taking better steps to cover all the aspects in their original filings, leaving little room for further scrutiny.

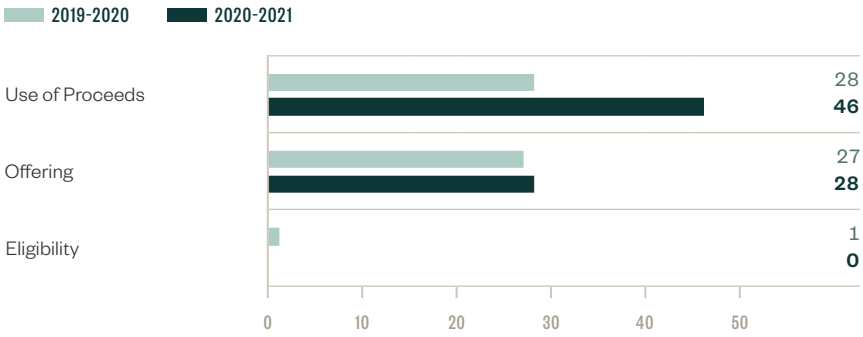
Sample Comments

> *You indicate that the [date] second amendment to the lease agreement is not included in the operating lease commitments as of [date]. If the cash lease payments under this amendment are material, please expand your footnote to present these payments using the same timeframes stipulated in the table. We believe this information will provide increased transparency on your long-term lease obligations. Refer to Item 303(a)(5) of Regulation S-K and footnote 46 to SEC Release No. 33-8350.*

> *Please also discuss your auditor's going concern opinion in the Liquidity discussion in your MD&A, addressing your financial condition; the uncertainties you face, such as your need to obtain additional financing; and the consequences for your business if you are unable to obtain additional financing.*

IPO-RELATED DISCLOSURES

FIGURE 10: Number of Comments—By IPO-Related Disclosures Subcategory
S-1 Filings, 2019–2020 & 2020–2021



Comments related to the IPO transaction are always procedural in nature, asking registrants to make specific disclosures in relation to their offering as well as clarify intended use of proceeds.

The purpose is to ensure full clarity to investors when it comes to understanding the actual terms of the offering, which include details, such as:

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

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

IPO-related disclosures constituted 5.2% of total S-1 comments in 2020–2021, going down from a share of 8.2% in 2019–2020.

The SEC required registrants to make clear-cut disclosures in the cover page and prospectus summary on all offering terms as well as state the implications of certain conditions and events that may directly relate to the completion of the offering.

Additionally, registrants were asked to be specific in breaking down their intended use of proceeds from the offering, whether pursuing further product development, discharging certain debt obligations, or meeting other funding requirements. This

included addressing any impending funding shortages and explaining how they'd be addressed.

OFFERING

Comments related to the offering transaction constituted over 37.8% of total IPO-related comments in 2020–2021, slightly down from a 48.2% share in the previous report.

The SEC's scrutiny lingered on similar parameters, requiring registrants to make unambiguous disclosures on their offering throughout the prospectus. Key areas for disclosures included the following:

- Adequate description of securities on offer, including determination of price and number of securities to be registered, as well as termination date
- Design, disclosure, and cross-referencing of the Cover Page, pursuant to Item 501 of Regulation S-K
- Classification of the offering, basis current shareholding, and all prevailing circumstances
- Over-the-counter (OTC) markets that the common stock was currently quoted on or may be quoted following completion of the offering
- Registration of the offering under the Exchange Act and consequent implications
- Clarification of underwriting arrangements and the activities of selling shareholders, in relation to the offering
- Contingency provisions—in other words, whether the offering was contingent upon securing listing approval in a market

Additionally, the SEC required companies that had shares quoted on the OTC Pink Market to disclose a fixed price at which their shares would be sold until the time they're listed on a national securities exchange or quoted on the OTC Bulletin Board, OTCQX, or OTCQB. This also held true for other securities on offer that didn't appear to have an established market.

Sample Comments

> *We refer to comment 1 in our letter dated [date] and your disclosure that there can be no assurance your application to list your Class A common stock on the Nasdaq Capital Market will be approved. Please tell us whether the offering is contingent upon securing Nasdaq listing approval and if it is not, please revise your cover page to clarify this fact.*

> *Please note that the OTC Pink marketplace is not an established public trading market into which selling stockholders may offer and sell their shares of common stock at other than a fixed price. Accordingly, please revise your cover page disclosure and make corresponding changes elsewhere in the prospectus to disclose a fixed price at which the selling shareholders other than [shareholder name] will sell their shares of your common stock until your shares are listed on a national securities exchange or quoted on the OTC Bulletin Board, OTCQX or OTCQB, at which time they may be sold at prevailing market prices or in privately negotiated transactions. Refer to Item 501(b)(3) of Regulation S-K.*

> *Please revise your disclosure throughout to explain whether you'll be registering your common stock under the Exchange Act in connection with this offering. If not, then add a separate risk factor to explain that you will not be subject to the proxy rules under Section 14 of the Exchange Act, the prohibition of short-swing profits under Section 16 of the Exchange Act, the beneficial ownership reporting requirements of Sections 13(d) and (g) of the Exchange Act, and that your periodic reporting obligations under Section 13(a) will be automatically suspended under Section 15(d) of the Exchange Act to the extent that you have fewer than 300 shareholders.*

USE OF PROCEEDS

Ensuring a sound allocation of funds is always pivotal to avoid straying away from intended goals, funneling wastage, or running into idle cash. A clear plan of action needs to be laid out well in advance, especially with public funding routes.

Consequently, the SEC's scrutiny on use of proceeds, pursuant to Item 504 of Regulation S-K, maintains significant traction year-over-year. Comments pertaining to these disclosures made up over 62.2% of total IPO-related comments in 2020–2021, significantly increasing from a share of 50% in 2019–2020.

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

This requirement doesn't only pertain to proceeds undertaken for product development. Whether it's utilizing funds to fast-track trials, obtain regulatory clearances, pay transactional fees, discharge indebtedness, or pay off other capital expenditures, the SEC seeks concrete and transparent disclosures from registrants with respect to the intended use and amount of each.

Sample Comments

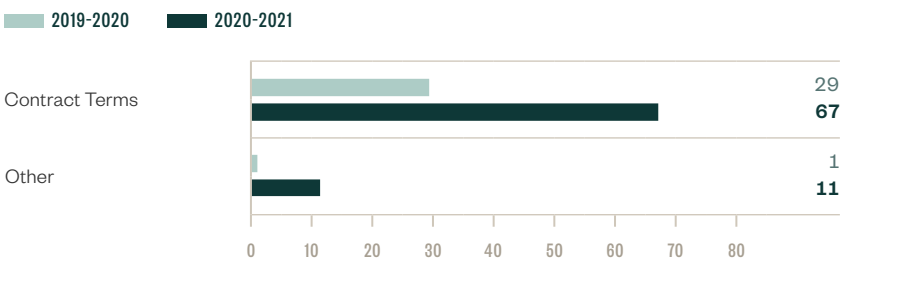
> *Please revise the discussion to identify the stage of development you expect to achieve with the proceeds of the offering for [product name] and [product name]. To the extent you expect to begin a particular stage of development but do not expect to complete it, please indicate that you will need to raise additional funding to complete that stage of development.*

> *We note your disclosure that you intend to use net proceeds to fund the development of [product name] and [product name]. Please specify how far in the development of each product candidate you expect to reach with the proceeds of the offering. If any material amounts of other funds are necessary to accomplish the specified purposes, state the amounts and sources of other funds needed for each specified purpose and the sources.*

> *Please revise to clarify whether any material part of the proceeds is to be used to discharge indebtedness. If so, please provide the disclosure required by Instruction 4 to Item 504 of Regulation S-K.*

LICENSES

FIGURE 11: Number of Comments—By Licenses Subcategory
S-1 Filings, 2019–2020 & 2020–2021



Focus on licensing agreements gained greater traction in 2020–2021 and made up 5.5% of total S-1 comments, up from a share of 4.4% in 2019–2020. It consequently emerged as the fifth largest category this period.

As competition in life sciences intensifies and the race toward innovation continues, strategic collaborations are becoming mainstream. Industry players are entering into license and research agreements as a means to accomplish the following:

- Reduce product development costs
- Speed up pipelines
- Share risks
- Capitalize upon expertise
- Generate synergistic relations

Given the vast variation in the nature and structure of license agreements—which often involve an array of activities within them—providing clear-cut disclosure around each agreement becomes imperative.

The SEC's scrutiny this period was very focused on having registrants disclose key parameters for each of their license agreements. Points of disclosure included the following:

- Material terms of the agreement, including each party's rights and obligations, agreement duration, nature of payments—including all upfront and milestone amounts—and termination provisions
- Nature, scope, and ownership of transferred intellectual property
- Royalty range, not exceeding 10 percentage points
- Expiration of the last of the patent rights licensed
- Existence of any material march-in-rights and their possible impacts
- Any impending restrictions or impact of the agreement to other parts of the business

In some cases, companies were also asked to describe how the licenses related to their product candidates and file the agreements as exhibits to the statement.

The overall focus here continues to be information clarity. The clearer companies are in describing the specifics of each agreement, the less likely they'll attract further scrutiny.

Sample Comments

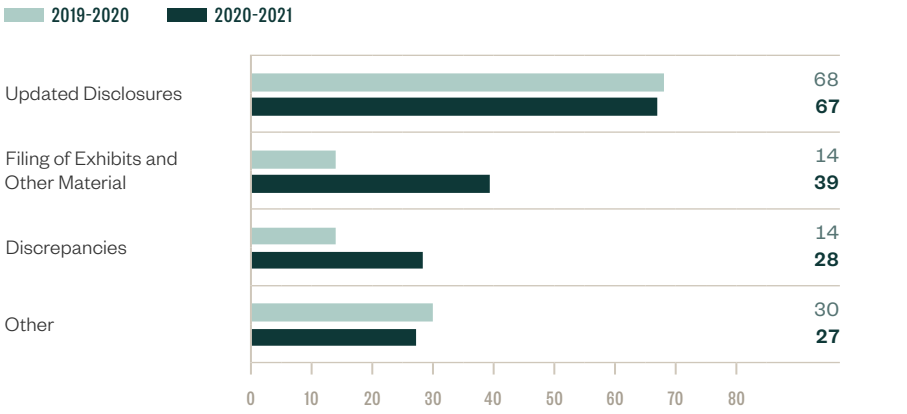
> *Please revise to disclose the amounts paid to date and when the royalty term is currently expected to expire. In addition, please revise your disclosure on the royalty range to disclose a royalty range of not more than 10 percentage points.*

> *Please briefly describe any of the material terms of the rights retained by the US government. If there are any material march-in-rights, address the portion of your business that would be impacted by exercise of such rights and describe the conditions which might prompt the US government to exercise any such rights. Include risk factor disclosure if appropriate.*

> *To the extent the performance benchmarks provide [party name] with a right to terminate the agreement, they appear material and require disclosure. Please revise to describe the benchmarks and applicable timeframe. Alternatively, explain the basis for your belief that the consequences of failing to meet a benchmark are not material.*

PROCESS COMPLIANCE

FIGURE 12: Number of Comments—By Process Compliance Subcategory
S-1 Filings, 2019–2020 & 2020–2021



Process compliance is a critical component for every business pathway, whether it involves expanding into new markets and products, or furthering capital expansion routes. In the IPO domain, this area is extremely important for S-1 applicants that are drafting disclosures for going public for the first time.

IPO registrants often end up with a large number of comments on their filings, in which they're required to add or modify several sections of their prospectus and comply with requisite regulations.

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

The SEC has recently introduced a host of amendments in Regulation S-K under its modernization drive, in an attempt to simplify disclosure requirements while enhancing information transparency and materiality. This specifically includes changes made to Items 101, 103, 105, 301, 302, and 303 that have significantly streamlined process compliance for companies under a principles-based approach.

Given market and regulatory dynamism, developments like these are inevitable. Sometimes such changes would be more based on law, sometimes more on fact, or sometimes completely procedural. The SEC's recent adoption of rules to facilitate electronic submission of documents by permitting electronic signatures for filing is just one of the many changes that aim to keep procedural formalities in line with current technology, and social conditions. This means adding flexibility, where necessary, while retaining authenticity and reliability.

It's up to companies to stay abreast of all amendments and updates and make requisite modifications in their standard disclosures. This stance toward active compliance can consequently keep SEC scrutiny quite active in this domain.

In 2020–2021, comments related to process compliance totaled 161, making up 11.3% of total S-1 comments. While this was a significant decrease from a share of 18.4% in 2019–2020, this category still made up the third largest category of comments for S-1 filings.

Similar to the last study, a vast variety of areas were examined within this larger sphere, such as:

- Accepting accountability for information presented in the filing
- Dealing with confidential treatment requests
- Providing proofs of graphics and design
- Submitting the requisite signatures

Comments were focused on correcting discrepancies, ensuring exhibits were filed correctly and comprehensively, and making updated disclosures.

DISCREPANCIES

Discrepancies can become a significant issue in a typical-sized prospectus. Given the sheer length and breadth of the document with multiple sections and points of disclosure, the likelihood of inconsistencies is quite high. Consequently, the SEC continues to scout for such deviations every year, having registrants revise requisite disclosures throughout to make sure all information is in sound agreement.

Comments related to discrepancies made up 17.4% of total process compliance comments in 2020–2021, up from a share of 11.1% in 2019–2020.

Similar to the previous study, discrepancies arose in a variety of areas. This ranged from disclosures regarding the following:

- Products in development
- Clinical trials
- Market estimates
- Election under the Jumpstart Our Business Startups (JOBS) Act
- Share conversion terms
- Exclusive forum provisions
- Warrant redemption
- Selling stockholders
- Reference documents

Registrants often made certain claims in the Business and Management sections that conflicted with the disclosures made in Risk Factors. Similarly, certain claims made about products in development didn't gel well with trial results.

Companies are advised to carefully go through all information provided across all sections of the prospectus, making sure to avoid conflicting statements.

Sample Comments

> *Please reconcile the disclosure in this section with the disclosure contained in the last risk factor on [page reference]. In this regard, we note that your federal exclusive forum provision disclosure appears inconsistent, namely by identifying different federal jurisdictions for the adjudication of claims.*

> *We note your disclosure in this risk factor that the selling stockholders have expressed an intent not to sell stock concurrently with the primary offering. However, we also note that the Selling Stockholder table on [page reference] of the Selling Stockholder Prospectus reflects that the selling stockholders expect to offer all of their shares in the offering. Please explain or revise to reconcile these disclosures as necessary.*

> *The disclosure here refers to a 10-for-1 reverse split while other places in the registration statement refer to a 1-for-10 reverse split. Please revise the disclosure to remove this discrepancy.*

FILING OF EXHIBITS & OTHER MATERIAL

Comments related to filing exhibit material made up 24.2% of total process compliance comments this period, significantly up from a share of 11.1% in 2019–2020.

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

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

Accordingly, registrants this period were asked to file as exhibits all material contracts related to licenses, employment, supplier, services, credit, and common stock agreements, as well as auditor consents. In case of any amendments, they were asked to file the most updated agreement.

The objective of Item 601 is largely centered around materiality. Registrants must file documents pertaining to all material agreements or otherwise provide an analysis of why they believe certain arrangements aren't material enough to be included as an exhibit.

Given that these companies don't have previous filings on EDGAR, the provision of key information filed as exhibits is pivotal.

Sample Comments

> *Please file as exhibits to your registration statement copies of your line of credit agreements, including those entered into on [date], or tell us why you believe you are not required to do so. Refer to Item 601(b) of Regulation S-K.*

> *Please obtain and file a currently dated consent from your independent registered public accounting firm with your next amendment.*

> *Please tell us how you determined none of your leases were required to be filed under Item 601(b)(10) of Regulation S-K.*

UPDATED DISCLOSURES

One of the most dominant areas under process compliance every year is the broad-based subcategory of Updated Disclosures.

Comments here totaled 67 in 2020–2021, making up 41.6% of the process compliance mix. While this was a moderate drop from a share of 54% in 2019–2020, this area continued to garner the greatest attention in process compliance.

Similar to previous years, the nature of SEC scrutiny was centered upon updated information, requiring registrants to make various disclosures across different parts of the prospectus.

The nature of disclosure was quite wide, asking companies to make revisions, such as:

- Updating financial statements to include all changes that may have occurred between amended filings, which may have further included explaining what those changes were and why they were made
- Clarifying developmental and reporting assumptions to provide unambiguous procedural adherence
- Giving reasoning for compliance-related claims

- Including current business contact details and information platforms, such as any new websites or publications
- Discussing all recent market developments and how they could affect the business
- Making accurate regulatory representations, including the applicability of safe harbor provisions
- Cross-referencing facts and figures quoted previously, making sure all changes corroborated well
- Providing all material information for every topic covered within the prospectus itself, instead of simply referring to external sources
- Reflecting adoption of new and amended items of Regulation S-K, pursuant to the SEC's modernization drive

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

It's vital for registrants to provide the scope of this action and its enforceability on potential claims.

Sample Comments

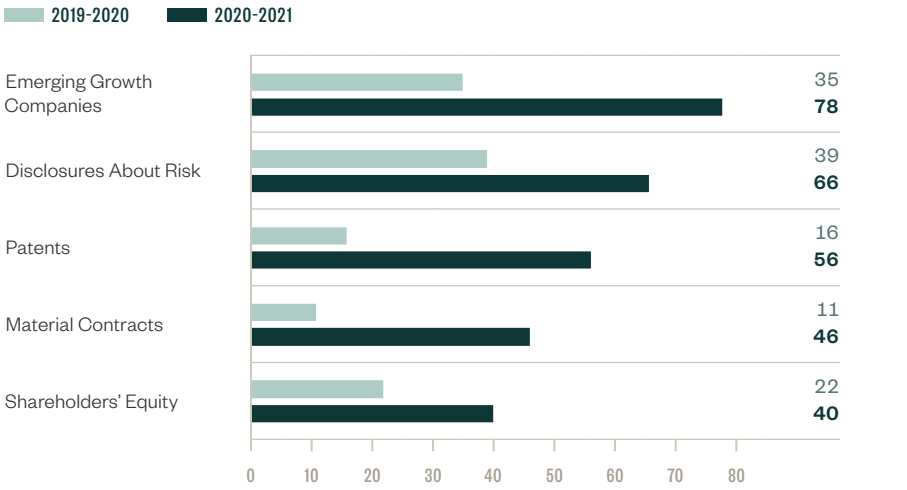
> *We note that your forum selection provision identifies the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation, including any "derivative action." Please disclose whether this provision applies to actions arising under the Securities Act or Exchange Act. In that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

> *Revise to include audited financial statements for the fiscal year ended [date]. For guidance, refer to the Division of Corporation Finance's Financial Reporting Manual 1220.3.*

> *With reference to Release No. 33-10825, please revise your disclosure to reflect the amendments to Item 101 of Regulation S-K, which became effective as of November 9, 2020, including Item 101(c)(2)(ii).*

OTHER DISCLOSURE TOPICS

FIGURE 13: Number of Comments—Related to Other Disclosure Topics
S-1 Filings, 2019–2020 & 2020–2021



A wide range of other topics were covered in SEC comments directed at S-1 filings in 2020–2021, including comments related to the following:

- Emerging-growth company (EGC) status
- Risk-based disclosures
- Patents
- Material contracts
- Shareholders' equity

Together, these comprised over 20% of total S-1 comments.

EMERGING GROWTH COMPANIES

The JOBS Act enabled small businesses to go public under the EGC status. This status allowed these businesses, among others, to have less expansive disclosures than those required by non-EGC companies and to defer compliance with certain SEC reporting requirements.

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

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

A total of 78 comments were directed toward EGCs this period, with the ratio of comments increasing from 2019–2020, making up 5.5% of the S-1 mix. The SEC continued to ask registrants to provide copies of all written communications, as per Rule 405 of the Securities Act, and requested them to clarify their EGC status and elections.

Sample Comments

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

> *Please update the front cover page of your registration statement and the front cover page of the prospectus to reflect your disclosure on [page reference] that you are an emerging growth company and that you have elected to use the extended transition period for complying with new or revised accounting standards pursuant to Section 7(a)(2)(B) of the Securities Act. Refer to Form S-1.*

RISK DISCLOSURES

Risk is an inherent part of any business, in any industry. COVID-19 has made it especially clear that no one is immune when it comes to dealing with uncertainty or rapid change. Companies consequently need to provide a balanced disclosure of both opportunities and underlying risks.

While comments related to risk increased significantly, their relative share went down from the previous study—making up 4.6% of S-1 comments in 2020–2021 versus 5.7% in 2019–2020. Despite this, the SEC's focus here continued to remain significant.

Registrants were asked to clearly disclose all material risks associated with their business, including the following:

- Clinical trials
- Sufficiency of funds
- Intellectual property
- Cybersecurity
- Impending lawsuits
- Ownership
- Key managerial personnel
- Internal controls

This included comprehensively describing what each risk was, its consequences to entity-wide operations, and any remedial steps taken to mitigate effects.

Given the massive impact of COVID-19 on clinical trials and development pipelines, many companies were asked to elaborate on exactly how the pandemic disrupted their operations and their future plan of action.

The SEC continued to emphasize compliance with Item 105 of Regulation S-K, which is the current regulation governing risk-factor disclosures after modernization amendments. In accordance with a principles-based approach, registrants are encouraged to discuss the significant risks—as opposed to generic risks—affecting their business and keep the disclosure precise and concise.

Consequently, the SEC directed many registrants to narrow down their risk descriptions and be more company-specific on impacts to their business. Any discussion of generic risks was asked to be moved to the end of the section, under the General Risk Factors caption.

Sample Comments

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

> *We note your disclosure on [page reference] that your "clinical trials have been and may continue to be affected by the COVID-19 pandemic." Please revise the referenced risk factor to discuss in greater detail how your clinical trials have been affected.*

> *Please disclose in the Risk Factors Summary on [page reference] that you have on hand funds sufficient to fund your operations only into January 2021. Please make a conforming revision to the going concern risk factor on [page reference].*

PATENTS

Comments related to patents made up 3.9% of total S-1 comments in 2020–2021, up from a share of 2.3% in 2019–2020.

Similar to previous years, the SEC's scrutiny was largely centered upon key standard areas of disclosure. Registrants were asked to expand upon their patent portfolio descriptions, detailing factors, such as:

- Number of patents held or applied for
- Specific products or technology to which each patent relates
- Whether the patent is owned or licensed
- Type of patent protection
- Patent expiration dates and expected expiration dates for pending applications
- Jurisdictions where patents have been issued or have pending applications, including foreign jurisdictions
- Any risks associated with securing patent protection and related possible implications, including any impact associated with third-party patents or patent applications

Given the importance of securing intellectual property rights in this competitive and time-sensitive life sciences environment, the relevance of comprehensive disclosure is considered to be of paramount importance.

Sample Comments

> *With respect to all of your patents and patent applications, including those licensed from [entity name] to the extent not described elsewhere, please revise your discussion on [page reference] to state (i) the specific products, product groups, and technologies to which such patents relate, (ii) whether the patents are owned or licensed, (iii) the type of patent protection (composition of matter, use, or process), (iv) patent expiration dates, and (v) identify the jurisdiction(s) covered.*

> *We note your risk factor discussion on [page reference] regarding various third-party patents and patent applications that may affect your product candidates. To the extent that any such third-party patents or applications may have a material effect on any of your product candidates, please expand your disclosure here to discuss.*

MATERIAL CONTRACTS

With strategic collaborations and partnerships continuing to accelerate for life sciences companies, the influx of agreements and contracts also ramps up the disclosure requirements for such contracts, especially material contracts.

Comments related to material contracts more than tripled in number from last period, constituting 3.2% of the S-1 mix in 2020–2021. This was up from a share of 1.6% in 2019–2020.

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

Such disclosure of material terms, similar to license agreements, largely revolved around the following parameters:

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

The question of materiality remains the key factor for discussion and decision here. Registrants must thoroughly scan through all agreements and gauge their materiality to their operations to decide the extent of disclosure warranted. Generically, material contracts may include the following:

- Any exclusive agreements undertaken with certain stakeholders, such as suppliers, customers, and manufacturers
- Strategic research collaboration or grant agreements with other entities or government institutions
- Technology- and platform-sharing contracts
- Distribution agreements

This can include agreements with major suppliers and customers that have a material impact on business operations.

Ultimately, any agreement that affects or can significantly affect metrics—such as revenue, cost, intellectual property, or developmental pipelines—should be thoroughly described.

Concurrently, making references to any agreements in the prospectus summary also implies its sense of materiality to the business. The SEC expects registrants to describe the material terms of such agreements in an appropriate section of the prospectus and file them as exhibits unless they provide reasoning otherwise.

While the 2019 modernization amendments reduced the burden of reporting certain information that may be competitively sensitive, they don't remove the onus on filers to disclose all information that's material to investors.

Sample Comments

> *You disclose that you have established exclusive arrangements with [supplier type] medical supplies manufacturers mainly focusing on face masks, linens, bedding, gloves, and gowns, and that you've been "receiving approximately [amount] online orders per day for facemasks and hand sanitizers in a number of larger, wholesale orders." Please revise your disclosure to describe the material terms of these arrangements.*

> *We note your references in the Summary to various collaboration agreements and partnerships, but you have not filed any of these agreements as a material agreement, and you have limited disclosure regarding the terms of these arrangements in your Business section. To the extent these aren't material agreements, please explain why it is appropriate to reference these arrangements in the Summary. To the extent they are material, please revise your disclosures as appropriate to disclose all material terms and file such agreements.*

SHAREHOLDERS' EQUITY

Comments related to shareholders' equity made up 2.8% of the S-1 mix in 2020–2021, which was slightly down from a 3.2% share in 2019–2020. Despite the relative decline, this area remained a considerably important topic of focus.

Equity is a key component within a company's capital structure, directly driving both interest and control dynamics. Providing concrete disclosure on current equity structure, as well as any impending expected changes, remains paramount.

The SEC's scrutiny this period continued to focus on the following:

- Beneficial ownership percentages
- Activities of selling shareholders
- Underlying equity value in the proposed offering

This also included the models used to derive the fair value of common stock by having registrants disclose the methodology and assumptions applied.

Similar to the previous period, convertible preferred stock remained the center of attention. Registrants were asked to do the following:

- Describe the terms and triggers of each type of conversion
- Provide its effect on common stock value and control
- Highlight the extent of possible dilution

In cases of disparity, the SEC asked registrants to include a table comparing the public contribution under the proposed public offering and the effective cash cost to officers, directors, promoters, and affiliated persons of common equity acquired by them in transactions since inception, pursuant to Item 506 of Regulation S-K.

Sample Comments

> *Please expand footnote (1) to explain how you determined the number of common shares included in your pro forma earnings per share related to the automatic conversion of your preferred stock. In this regard, it appears that the changes made to the conversion terms of your Series A, B, and C preferred stock subsequent to [date] resulted in changes to the number of common stock issuable upon conversion as disclosed on [page reference]. Address this comment as it relates to footnote (1) to your Selected Financial Data.*

> *Please ensure that you have identified the natural persons who have or share beneficial ownership of the securities held by each of the entities listed in your table.*

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

Overall, comments directed toward Forms 10-K, 10-Q, and 20-F comprised roughly 5% of the total 1,497 comments analyzed in 2020–2021, which was a significant decline from a 14% share witnessed in 2019–2020.

Topics such as process compliance and MD&A continued to remain in focus, while ICFR gained greater footing from the previous study. Together, these made up 42 of the total 73 comments.

Examination of R&D activities and disclosure controls and procedures stood next in line, followed by a marginal number of other comments that were rather sporadic in nature.

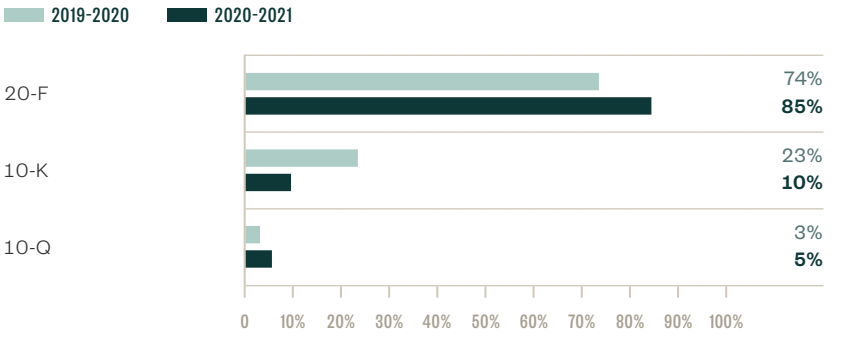
Contrary to the nature of scrutiny for S-1 filings, a greater focus was placed upon companies' ongoing operational results and performance as well as the efficacy of their internal processes and controls. Comments related to process compliance also differed, with a greater emphasis placed upon disclosure consistency and stipulated certifications.

FIGURE 14: SEC Comments Categories for 10-K, 10-Q & 20-F Filings
10-K, 10-Q & 20-F Filings, 2020–2021

29% Process Compliance
18% Management's Discussion and Analysis
11% Internal Control Over Financial Reporting
8% Research and Development
7% Disclosure Controls and Procedures
27% Other

73 Total Comments

FIGURE 15: Ratio of Comments—By Filing Type
10-K, 10-Q & 20-F Filings, 2019–2020 & 2020–2021



Form 10-Ks attracted the greatest SEC scrutiny among all the three filings in 2020–2021, constituting 85% of the total 73 comments. This was followed by Form 10-Qs garnering 10% of the mix and Form 20-F with the remaining 5%.

FIGURE 16: Key Areas of SEC Focus for 10-K, 10-Q & 20-F Filings—By Number of Comments
10-K, 10-Q & 20-F Filings, 2019–2020 & 2020–2021

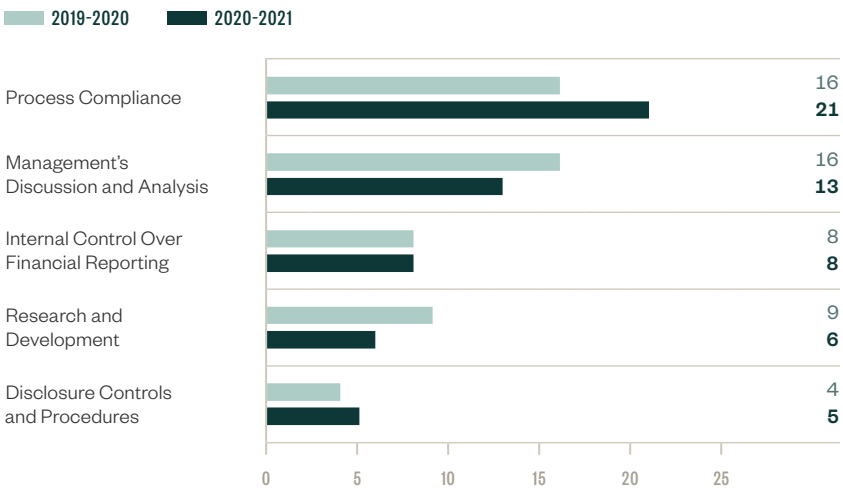
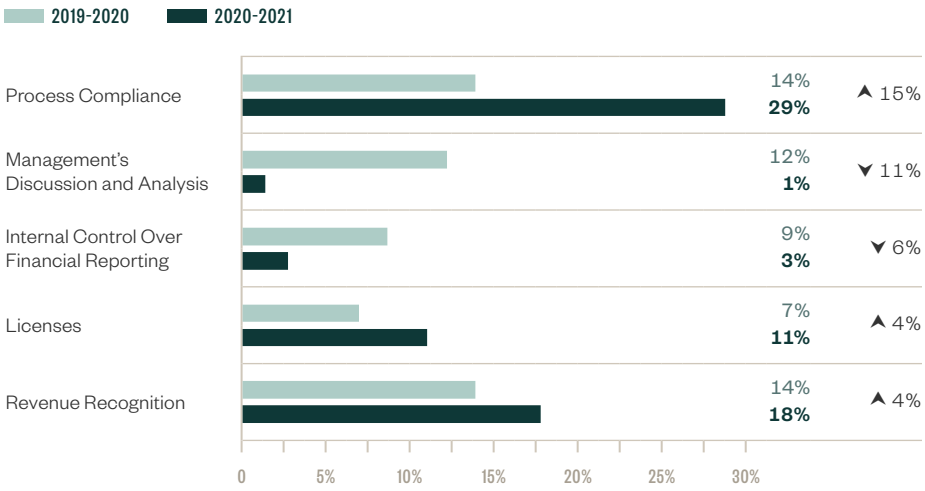


FIGURE 17: Significant Shifts in SEC Focus for 10-K, 10-Q & 20-F Filings—By Ratio of Comments
10-K, 10-Q & 20-F Filings, 2019–2020 & 2020–2021



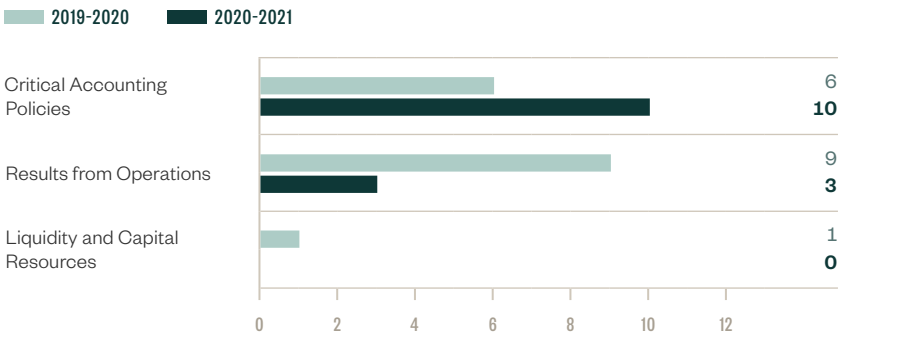
In comparison to 2019–2020, SEC scrutiny around process compliance significantly grew by 14.9% while comments on ICFR and MD&A increased by 4% and 3.9%, respectively.

Contrastingly, focus on revenue recognition and licensing agreements dropped by 10.8% and 6%, respectively.

Nevertheless, these shifts shouldn't be construed as a reflection of what's important to cover in filings. For example, a drop in comments related to revenue recognition doesn't mean there's a lesser need for disclosure on this subject. A declining number of comments may simply suggest that companies are taking better steps to cover all needed disclosures in their filings, leaving little room for further scrutiny.

MANAGEMENT'S DISCUSSION & ANALYSIS

FIGURE 18: Number of Comments—By Management's Discussion & Analysis Subcategory
10-K, 10-Q & 20-F Filings, 2019–2020 & 2020–2021



Regardless of how long a company has been public, providing comprehensive disclosure of operational performance, year-over-year, remains pivotal. Change is inevitable in any operating environment, and this accordingly shapes the trajectory of all companies.

Consequently, comments related to MD&A made up 17.8% of the 73 comments directed toward post-IPO filers in 2020–2021, up from a share of 13.9% in 2019–2020.

Similar to the previous study, the SEC required companies to provide a detailed discussion pertaining to material changes in operational results and present a quantified analysis of significant drivers. This included, for example, clearly discussing whether changes in net product sales occurred due to a movement in price or volume and trying to quantify the effect of each.

In cases of significant increase or decrease in any key performance metrics—product sales, cost of goods sold, or administrative expenses, for example—filers were asked to provide greater clarity on the underlying reasoning and zero in on concrete factors that contributed to the fluctuation, such as:

- Product type
- Royalty amounts
- Employment costs
- Lawsuits
- Other contingencies

The SEC emphasized that such disclosures should further be complemented with more holistic expectations going forward, based on management's identification of key trends and uncertainties that could materially affect the course of operations.

The use and explanation of critical accounting policies was particularly relevant here. The SEC requested many companies to clearly disclose their methodologies and assumptions in accounting for various types of business activities, such as:

- Collaborative agreements
- R&D costs
- Subsidiary statements
- Revenue generation

Many were also asked to provide the rationale behind their asset valuations—including those of intangibles and core inventory—as well as take greater care to avoid contradicting previous approaches. This reasoning included citing the authoritative literature relied upon and explaining its relevance in the particular situation.

Given the recent amendments made to Item 303 of Regulation S-K, as touched upon in detail in the prior S-1 MD&A section, the concept of materiality remains prime. While the modified rules provide greater flexibility to filers, they also place greater responsibility on them. Under the principles-based approach, companies can decide the best possible route to communicate information under MD&A. However, the onus on providing comprehensive material disclosures and upholding information transparency can't be compromised.

Sample Comments

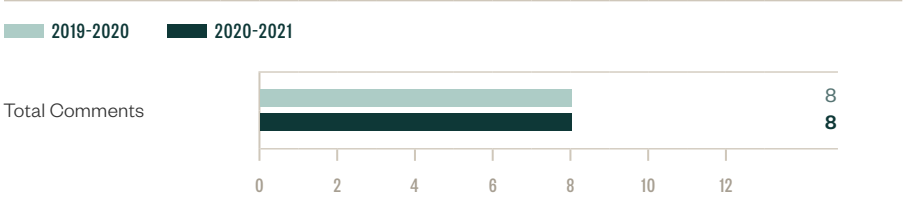
> *When discussing changes in net product sales confirm that in future periodic reports you will separately quantify the effect of prices from the effect of volumes sold.*

> *We see that you recorded the [date] loss on disputed inventory as a non-operating expense. Please tell us your basis for concluding transactions related to your core business model of selling inventory should be reported outside of operations.*

> *We note your disclosure that inventories are carried at the lower of cost or market. Please tell us how this is consistent with ASC 330-10-35-1B, which indicates that inventories should be valued at the lower of cost or net realizable value. Alternatively, revise your disclosures in future filings to state, if true, that inventories are stated at the lower of cost or net realizable value.*

INTERNAL CONTROL OVER FINANCIAL REPORTING

FIGURE 19: Number of Comments—By Internal Control over Financial Reporting Subcategory
10-K, 10-Q & 20-F Filings, 2019–2020 & 2020–2021



Internal controls refer to those specific procedures, processes, and activities within a company that ensure compliance with its policies. Within this, one key set of internal control systems refers to those that affect a company's financial reporting, helping ensure true and accurate statements for external stakeholders.

ICFR has a critical role in promoting information transparency. This came to the forefront during past major corporate and accounting scandals, which radically shook investor confidence. Since then, this area has been formally mandated under the Sarbanes-Oxley Act (SOX), requiring public companies and their top management to comprehensively disclose financial and accounting practices.

ICFR is specifically codified under Item 308 of Regulation S-K, which outlines management's responsibility and annual disclosure requirements around the same.

In absolute numerical sense, comments related to ICFR remained the same over the last two years. However, the relative importance of this category increased. ICFR-based comments made up roughly 11% of the total post-IPO mix in 2020–2021, up from a share of 7% in 2019–2020.

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

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

Apart from the disclosure itself, certain comments were also directed toward the applicability of this disclosure.

While the SEC has established a transition period for compliance for newly public companies, this applies to only the first annual report. Companies must accordingly exercise caution when claiming such transition and confirm applicability before filing.

It's also important to note that this disclosure is distinct from disclosure controls and procedures required by Item 307 of Regulation S-K. Assessment of these parameters should be conducted separately.

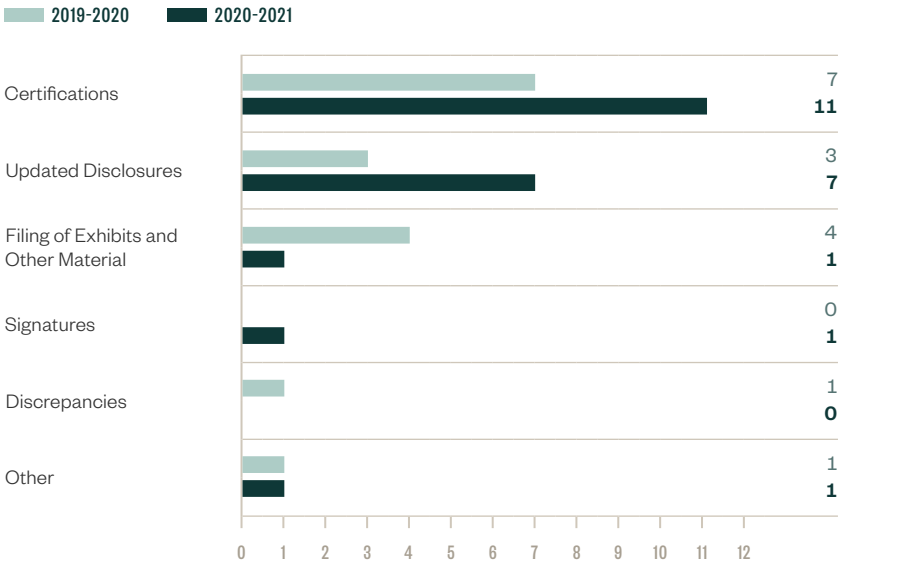
Sample Comments

> *Please amend your Form 10-K to provide management's report on internal control over financial reporting as of [date] as required by Item 308(a) of Regulation S-K. Include the framework management used to evaluate the effectiveness of internal control over financial reporting and a definitive conclusion as to their effectiveness in accordance with Items 308(a)(2) and 308(a)(3) of Regulation S-K.*

> *You state that a report of management's assessment regarding internal control over financial reporting is not included "due to a transition period established by rules of the Securities and Exchange Commission for newly public companies." Please tell us your consideration of Item 308(a) of Regulation S-K, particularly the Instructions thereto, which indicate that such transition period would apply to only the first annual report. Alternatively, amend your filing to so provide.*

PROCESS COMPLIANCE

FIGURE 20: Number of Comments—By Process Compliance Subcategory
10-K, 10-Q & 20-F Filings, 2019–2020 & 2020–2021



Focus on procedural compliance grew stronger for post-IPO filers this period. The ratio of comments directed toward process compliance significantly increased by 14.9% from the previous report.

Similar to the S-1 category, while comments here are generally formulaic and administrative in nature, they do make up a sizable volume each year. The importance of this area can't be overlooked because it may become a cause for filing delays.

The specific nature of scrutiny here continued to center on certifications. Companies were largely required to revise their Section 302 certifications to include the introductory language in paragraph 4 referring to their ICFR as well as paragraph 4(b), which referred to the design of internal reporting. Additionally, filers were also required to file complete Section 906 certifications or revise their existing certifications to comply with specifications under Item 601 of Regulation S-K.

This was followed by a focus on updated disclosures, which included a broad range of comments requiring companies to bring greater clarity to their filings. The SEC required companies do the following:

- File all requisite financial statements in accordance with Regulation S-X
- Clarify any adjustments made within a statement
- Specify exclusive forum provisions

Comments related to signatures, discrepancies, and filing of exhibits were minimal and sporadic.

On a broader level, compliance has and will remain a key topic of focus for any type of company: pre- or post-IPO. Accordingly, SEC scrutiny can be expected to continue as companies reshape their practices to align with changing regulatory dynamics.

Sample Comments

> *Please confirm to us that your future filings will include complete Section 906 certifications, referencing compliance with the requirements of both Section 13(a) and Section 15(d) of the Securities Exchange Act of 1934.*

> *We note that your Form 10-K contains management's internal control report on [page reference] as required by Item 308 of Regulation S-K. Your Section 302 certifications should include the introductory language in paragraph 4 referring to your internal control over financial reporting as well as paragraph 4(b), which refers to the design of your internal reporting. Please note that you are no longer in the transition period that allows for this omission. Please file an amendment to your Form 10-K that includes updated Section 302 certifications that comply with Item 601(b)(31)(i) of Regulation S-K. You may provide an abbreviated amendment that consists of a cover page, explanatory note, signature page, and paragraphs 1, 2, 4, and 5 of the certifications. Please note that this comment also applies to Form 10-Qs filed in 2019.*

> *We note that Article IX, Section 7 of your Third Amended and Restated Bylaws identifies the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation, including any "derivative action." In future filings, please prominently describe the provision, including the relevant forum for litigation and any subject matter jurisdiction carve out, and whether this provision applies to actions arising under the Securities Act or Exchange Act. If so, please also state that there is uncertainty as to whether a court would enforce such provision and include risk factor disclosure of the risks to investors, such as the increased costs to bring a claim and that the provision may discourage claims or limit investors' ability to bring a claim in a judicial forum that they find favorable. Further, if the provision applies to Securities Act claims, please also state that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. In that regard, we note that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.*

OTHER DISCLOSURE TOPICS

R&D

Comments related to R&D made up 8.2% of the post-IPO mix in 2020–2021, slightly up from a share of 7.8% in 2019–2020.

Similar to the previous study, the SEC requested that companies provide more balanced disclosure on their clinical trials, including all SAEs observed. Additionally, expenses were a big feature this period. Many companies were requested to elaborate on the nature of R&D expenses incurred each year, disaggregate expenses by product or program type, and reason out any significant fluctuations.

Sample Comments

> *You present a table of direct and indirect costs on [page reference] and disclose on [page reference] that you allocate direct external costs to your product candidates. Considering that your product candidates are now in more advanced late stages of clinical trials, please provide disaggregated disclosure for external costs by product candidate or indication incurred for each period or tell us why additional disclosure cannot be provided.*

> *We note your reference to the most common serious adverse events on [page reference]. Please revise to describe all serious adverse events and disclose the frequency with which each type of serious adverse event occurred.*

DISCLOSURE CONTROLS AND PROCEDURES

Item 307 of Regulation S-K formally mandates disclosing conclusions of the company's principal executive and principal financial officers, or persons performing similar functions, regarding the effectiveness of its disclosure controls and procedures (DCP).

For the purposes of this section and as defined under federal regulations, DCP refers to "controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms."

Comments related to DCP made up 6.9% of the total 73 post-IPO comments this period, up from a share of 3.5% in 2019–2020. The SEC's scrutiny largely focused around having companies make comprehensive disclosure on DCP as it related to each component within the statutory definition.

In case of material weaknesses or ineffectiveness of internal controls, companies must discuss remediation plans and describe how long it would take to complete them.

Sample Comments

> *You disclose on [page reference] that [you] had failed to adequately invest in personnel and systems to accumulate, record, and properly report on [your] results of operations. Please explain to us if such failure amounted to material weaknesses to be disclosed similar to disclosures made in your Form 10-Q for the Quarter Ended [date]. Please tell us how management was able to conclude that your disclosure controls and procedures and your internal control over financial reporting were effective at [date] in light of your aforementioned disclosure and amend your filing if your conclusions were incorrect. In amending your filing, please assure that you discuss remediation plans in place to address the material weaknesses, including how long you estimate it will take to complete the plans, and estimated costs, if material.*

> *Your conclusion refers to only a portion of the definition of disclosure controls and procedures in Exchange Act Rules 13a-15(e) and 15d-15(e). In this regard, it appears your conclusion applies only to the portion referred to. Please confirm to us and revise to clarify, if true, that your conclusion is in regard to the entirety of disclosure controls and procedures as defined.*

MARKET CAPITALIZATION RANGE

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

Over 79% of Forms 10-K, 10-Q, and 20-F comments were centered on companies with a market capitalization of less than $500 million. Of the remaining, 6% were directed toward those with market capitalization between $500 million and $1 billion while 15% pertained to those greater than $1 billion but less than $2 billion.

Smaller companies continued to attract the greatest scrutiny.

FIGURE 21: Ratio of Comments—By Market Capitalization Range
10-K, 10-Q & 20-F Filings, 2019–2020 & 2020–2021

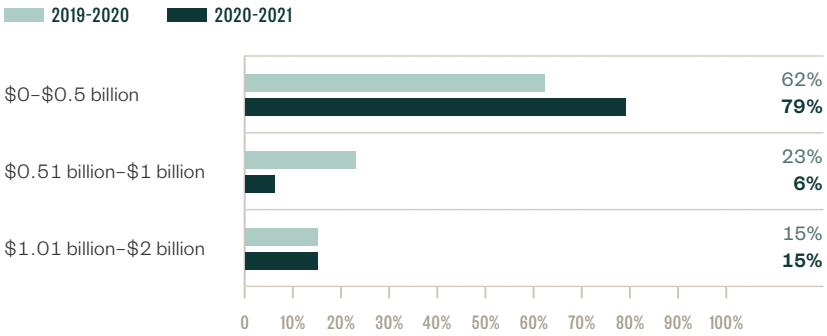
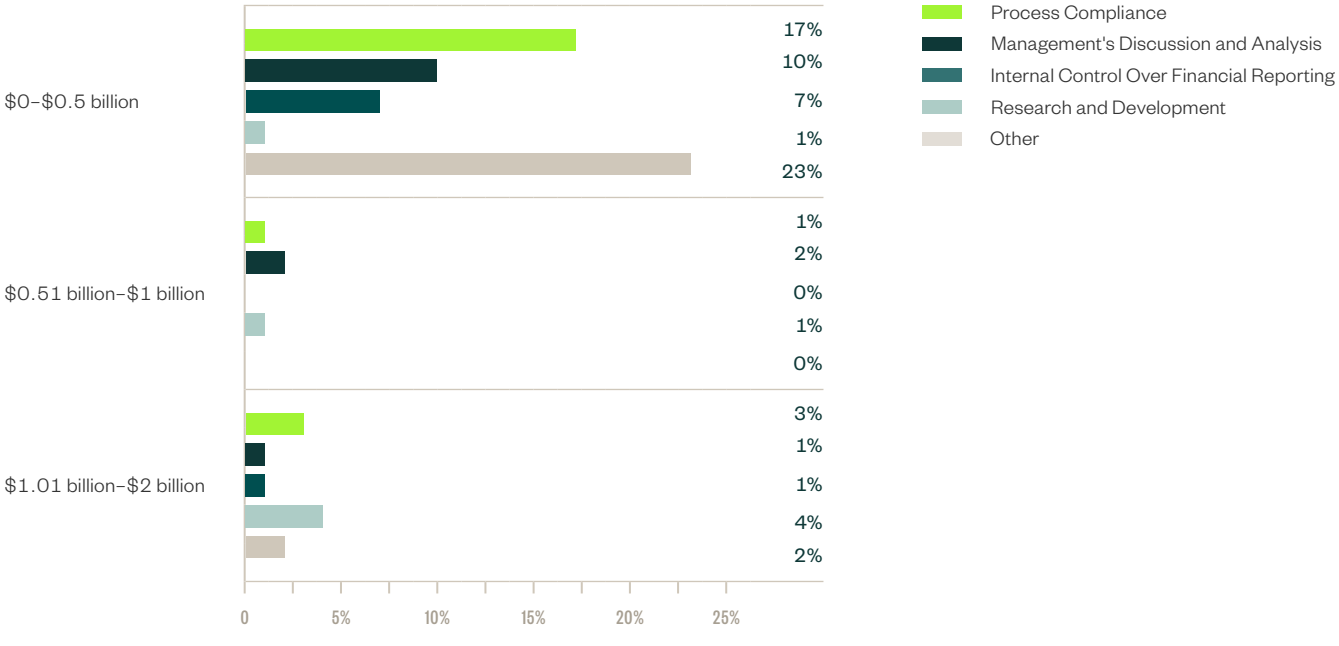


FIGURE 22: Trends in Comment Categories—By Market Capitalization Range
10-K, 10-Q & 20-F Filings, 2020–2021



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

This pattern can arise due to multiple reasons. First, new registrants that don't have prior experience in filing public disclosures can often run into compliance issues. They may require several iterations of filings before they get accustomed to the system.

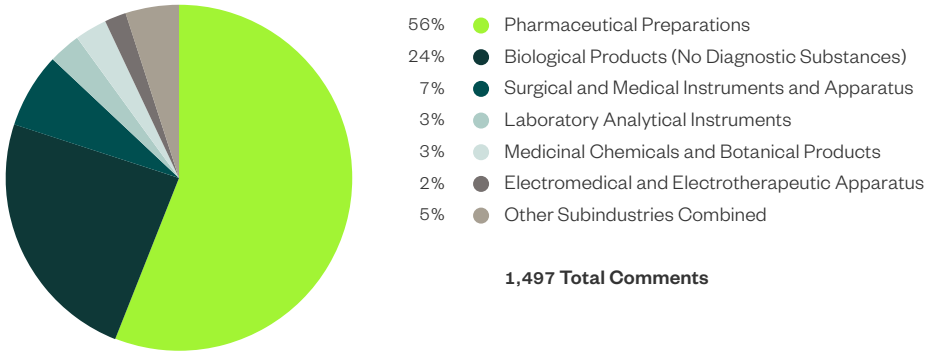
Second, small companies can sometimes face the largest gaps. These smaller companies have fewer resources to allocate toward compliance, whereas larger capitalized companies have greater resources, including more experience and in-house set-ups to help them maintain up-to-date compliance.

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

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

Subindustry Trends

FIGURE 23: SEC Comments—By Subindustry
S-1, 10-K, 10-Q & 20-F Filings, 2020–2021



Of all the subindustries analyzed in this study, pharmaceutical preparations continued to receive much of the SEC's focus. It made up 55.8% of total comments this period, a very slight decrease from a 56.7% share in 2019–2020. The extent of scrutiny, however, remained greater than any other subindustry. This wasn't surprising because 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-based value spectrum—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. Such responsibility becomes even bigger for S-1 registrants that have a larger disclosure ambit to meet in the first place.

Biological products stood as the next most significant subindustry with an aggregate comment share of 23.7%, followed by surgical and medical instruments and apparatus at 7.3%.

Similar to the previous study, there has been an interesting shift of dynamics within these two categories. While the ratio of comments for biological products went up considerably by 7.8% from 2019–2020, surgical and medical instruments and apparatus went down by 9.6%.

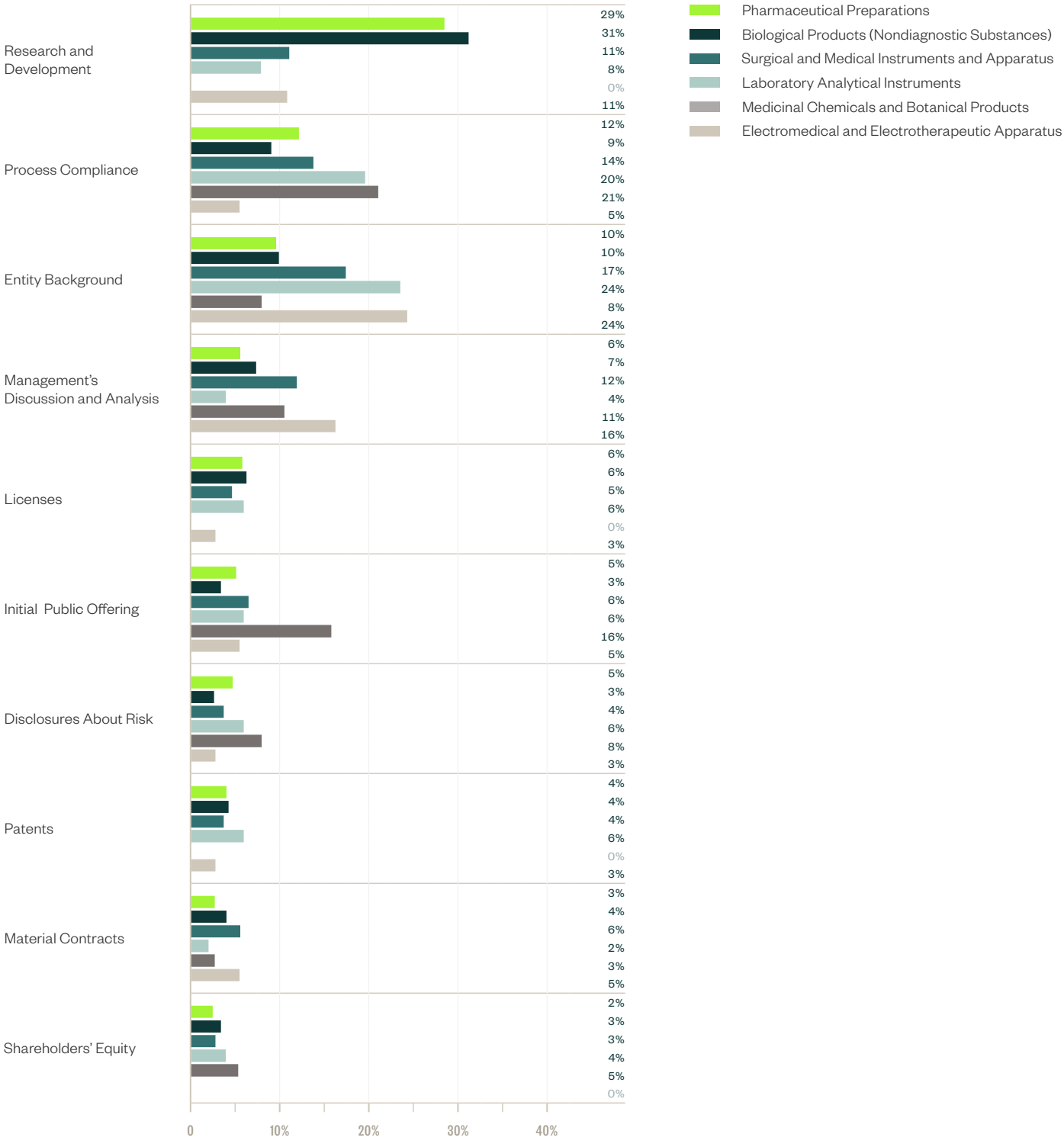
A mix of various other subindustries followed afterwards, though with relatively smaller shares of less than 5% each.

Laboratory analytical instruments, which didn't attract any relevant comments in 2019–2020, garnered 51 comments this period.

NATURE OF COMMENT CATEGORIES

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

FIGURE 24: Share of Comment Categories—By Subindustry
S-1, 10-K, 10-Q & 20-F Filings, 2019–2020 & 2020–2021



Compliance is a core component of public filings that continues to affect all companies, regardless of industry or subindustry. Consequently, comments related to process compliance remained significant across subindustries, generally making up 10%–20% of the mix.

R&D has always been a focal area for life sciences companies, emerging into even greater prominence this period. Barring certain subindustries—such as medicinal chemicals and botanical products as well as x-ray apparatus and tubes and related irradiation apparatus—R&D generated a significant number of comments across companies. Within these, pharmaceutical preparations and biological products saw R&D-related comments making up a significant 30% of the mix. This largely pertained to the extent of developmental activities in this space, involving a range of clinical studies and long gestation periods.

Electromedical and electrotherapeutic apparatuses also saw an influx of R&D-related scrutiny this period, making up 25% of total comments.

Meanwhile, entity-related disclosures were relatively more important for subindustries like surgical and medical instruments and apparatus as well as laboratory analytical instruments.

It's worth noting that certain topics may attract greater scrutiny one year and less the year after. For example, companies in medicinal chemical and botanical products saw much less focus on shareholders' equity this period in comparison to the previous report, while comments related to IPO shot up in multiples. A similar story goes for electromedical and electrotherapeutic apparatuses, which saw entity-related comments almost tripling in share over the last period.

The key takeaway is that while there may be some topics that remain common for the entire sector, others will continue to vary among subindustries. Even within a subindustry, some categories may attract greater scrutiny in one particular year and backtrack the next. This depends on both market dynamics and timing, which may bring certain issues to the forefront and highlight efforts companies are taking to properly address these areas in their filings.

Companies need to stay abreast of the specificities of their own markets, paying close attention to inherent challenges or sensitivities that may require additional clarification. They also need to keep a close tab on changing macro-conditions on both global and local levels, understanding their effects on the business and whether they require further disclosure. Information clarity and transparency remain critical at all points during this process.

SECTION FIVE

Conclusion

As the clock continues to tick, it brings life sciences into a revolutionary shift. The entire industry—which was already witnessing massive change with innovation sprees, shortening product lifecycles, obsolescence, and rapid technological growth—has catapulted even more radically with the pandemic.

The search for novel therapies, whether it be for COVID-19 or other rare and underserved diseases, is in full swing. Companies are readily undertaking strategic collaborations, streamlining R&D, securing intellectual property rights, and designing appropriate commercialization plans as they battle with the race against time.

Going public has continued to be a key financing springboard for expansion in this regard, with a range of companies—big and small—filing applications to raise public capital and gain investor support.

SEC COMPLIANCE TRACKER

Maintaining sound regulatory compliance is a cornerstone for driving operational efficiency and reducing procedural delays.

A core part of maintaining compliance includes staying up to date with SEC standards and requirements, which are applicable from the first IPO registration statement through all subsequent filings required in the public domain.

Companies can benefit from taking the following actions:

- Creating informative and sound documents
- Providing clear and adequate disclosures on all critical matters
- Keeping investor confidence intact

With IPO activity running strong in the life sciences domain as a host of new players go public, 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.

This trend was observed in this 2020–2021 report, with the SEC seeking clarity from companies on a host of issues, ranging from making adequate disclosures and carrying out insightful discussions to providing a clear presentation of their information in filings.

POPULAR TOPICS

Areas like R&D and process compliance continue to stay at the forefront year-over-year. Given the nature of life sciences with significant research costs, developmental cycles, product pipelines, and regulations, disclosure in these topics is important.

Information around entity-wide operations is particularly important for first-time registrants making their debut in public markets. Meanwhile, discussion on

operational results, key business risks, and management's outlook is imperative for both pre- and post-IPO filers.

While these core comment categories continue to top the charts every year, what largely differed this time was the depth and breadth of disclosure required. Companies were asked to clearly describe how COVID-19 had impacted their operations over the last period—whether that was through disrupting ongoing clinical trials, prolonging developmental pipelines, changing the nature of operational focus, or bringing a new business model into play. It also included disclosing how they were pivoting their ways of doing work to adapt to the "new normal."

Making all these disclosures within stipulated SEC guidelines is a must. Adherence to Regulation S-K and Regulation S-X remains pivotal—for both pre- and post-IPO companies—and can be as simple as including the right signatures or filing the right documents.

WHY IT MATTERS

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

This report focuses on familiarizing life sciences companies with pertinent factors in their registration statements and filings by touching on core SEC comments made in these areas. 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 impending 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

To gain more insight into the SEC's comment process or to ask questions about how to prepare your company for its IPO, contact a Moss Adams professional.

About Our Life Sciences Practice
We serve organizations of all sizes—from large multinational companies and publicly traded middle-market corporations to private companies and start-ups. Our clients specialize in many areas, including:

- Biotechnology
- Diagnostics
- Medical devices
- Pharmaceuticals
- Digital health

Gain deep resources and industry expertise at every step of your business life cycle, whether you're facing an audit, needing to reduce risk, or preparing for an IPO Moss Adams is also the only middle-market firm with five professionals who served two-year terms as fellows at the SEC.

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