MOSSADAMS

Under the Microscope

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

2019

CONTENTS

INDUSTRY OVERVIEW

Initial public offerings (IPOs) in the Life Sciences industry gained steady momentum from 2018 to 2019 largely driven by the biotechnology boom.

MARKET REPLAY

Progressing Ahead of Expectations

The number of IPOs continued to grow in 2018 with 192 companies going public and raising $47 billion according to Renaissance Capital's United States market review. Deal count and proceeds rose by 20% and 32% respectively from 2017. However, the global selloff in the last quarter caused a substantive turnaround leading average IPO returns to slide down to -2%.

Despite the uncertainty in the beginning of the year, 2019 progressed better than expected with a robust second quarter delivering the most single-quarter deals since 2014. This led to 159 IPOs for the full year of 2019 raising $46 billion with average returns at +20%. While the deal count went down by 17% as compared to 2018, proceeds remained steady with deals aggregating $9 billion making headlines. Health care and technology continued to lead the activity accounting for over two-thirds of the issuances. Seven biotechnology companies went public at $1 billion-plus valuations.

While the recent outbreak of COVID-19 has cut IPO momentum short in 2020, the trajectory ahead will depend on how soundly markets are able to recover in the aftermath of the pandemic. A pressing need on sectors such as health care and technology should encourage more companies to expand their public footprint.

LIFE SCIENCES AT A GLANCE

While innovative drug development, intellectual property (IP) protection and regulatory bottlenecks continue to be key focus areas for life sciences companies, new health concerns, trade barriers, and heightened competition have also come to the forefront. Companies may need to restructure their business models, with a focus on effectively integrating digital technology, utilizing real world data (RWD), and involving patients at all points of the care spectrum.

Growing Research & Development

As a sector, life sciences has grown at its fastest pace since 2000 employing over 1.2 million workers in the United States. All subsectors, from manufacturing to testing labs, have seen an influx of employees and funding. The efforts towards Research & Development (R&D) grew by 88% over the last 20 years.

R&D is critical, and this can be observed in the 2018 through 2019 SEC filings. SEC scrutiny remained dominant with R&D-centric comments making up over 16% of the comments for Form S-1 filings. Focal points included applicants providing further disclosure on their critical studies and trials, developmental pipeline, and salient features of upcoming products. Giving a balanced picture on all research and ensuing drug candidates remained paramount.

Calibrating Compliance

Given the nature of the industry, regulatory compliance has always been a critical pillar. Regulatory compliance becomes even more complex with globally-dispersed

value chains and multi-dimensional consumer markets. Passive compliance isn't enough. Companies are embedding active compliance across all processes and activities which effectively calibrates into the main business strategy. Technology stands at the fulcrum, helping firms launch into new products and markets, go public, and pursue necessary funding channels with all checks intact.

A considerable amount of SEC focus was placed on regulatory and procedural compliance; 17% of SEC comments related to this area.

Pursuing the Pandemic Picture

The emergence of the COVID-19 pandemic has put the entire world on hold. Life sciences has come under immense pressure, with companies coming together to aggressively combat this threat. Fast-paced development—from coronavirus vaccines to treatments to testing kits—has become a new normal. R&D is in full swing, with many companies coming up with promising solutions that are being fast-tracked into clinical testing and trials.

Notwithstanding the current uncertainty, permanent trends include gearing the sector towards value creation, with a focus on patient protection, withstanding disruption, and helping support global economic recovery.

The quest for new ideas and innovation remains high, bringing in a greater number of players, collaborations, and investment despite the various challenges brought about by the COVID-19 pandemic.

SEC COMMENT LETTER REPORT

RATIONALE

Fast-paced development requires utmost care in managing operational compliance to minimize unnecessary time lags. In the domain of filings, there's a pressing need for companies to be aware of procedural requirements and core issues that have attracted, and continue to attract, greater scrutiny.

The objective of SEC comments is to bring greater transparency to investors, prevent discrepancies, and keep market confidence intact.

The rationale of this report is to identify, understand, and analyze comments made by the SEC in the past in order to obtain insights and encourage proactive preparedness.

This report specifically examines SEC comments issued toward S-1, 10-K, 10-Q, and 20-F filings in 2018 and 2019 to identify possible patterns and changes in relation to the last study of 2017 and 2018.

We hope to provide start-up, small capitalization, and middle-market life sciences companies—those with current market capitalizations of less than $2 billion as well as pre-IPO candidates looking to go public—with actionable data as they prepare their SEC filings.

METHODOLOGY

To perform our analysis, we categorized all SEC comments directed toward companies in select life sciences subindustries during the period of our review. The following subindustries—as identified by their EDGAR SIC code—were covered in our report:

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 & 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

The focus of our study was small capitalization and middle-market companies, so we excluded comments related to companies with market capitalization greater than $2 billion on the date of analysis from our research and assessment. Our analysis included comments filed on the SEC EDGAR database during the period from May 1, 2018, to April 30, 2019—referred to as 2018 and 2019 in the report.

Comments for the following SEC filings were considered:

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 enhanced the previous comments if not appropriately addressed.

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

We considered cases where shifts in comment ratios in a given subset of comments from 2017 and 2018 to 2018 and 2019 exceeded the mean variance in that subset to be significant variances over the last two years.

For example, out of the 180 comments directed toward 10-K/10-Q/20-F filings in 2017 and 2018, 22 were related to management discussion and analysis (MD&A) amounting to a ratio of 12.2%. The same ratio increased to roughly 20.9% in 2018 and 2019, signifying an increase of 8.7%. This was greater than the mean variance amongst other topics in 10-K/10-Q/20-F filings over the stipulated time period, so we considered the variance in MD&A-related comments to be significant.

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

Overall Trends

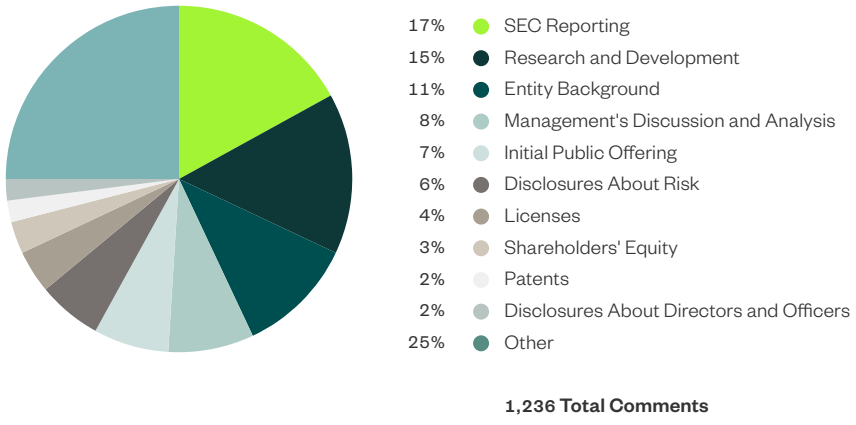
The number of SEC comments toward S-1, 10-K, 10-Q, and 20-F filings for 2018 and 2019 was approximately 1,236. These were largely spread across several key categories, but comments relating to SEC Reporting, or process compliance, were the most prominent garnering a 16.7% share. Comments related to SEC reporting tend to be more administrative and formulaic, but because of the sheer volume of such comments, companies have an opportunity to significantly reduce filing delays by understanding the nature of scrutiny under this topic and taking the appropriate steps towards compliance.

R&D was the next major category with a share of 15.3%. R&D comments relate to clinical trials and studies, Food and Drug Administration (FDA) filings and communication, product pipeline, products and services, and other highly company-specific information. The majority of comments in 2018 and 2019 were directed toward companies' clinical trials and studies, which was consistent to the 2017 and 2018 study. This was followed by comments requiring disclosure on entity-background, MD&A, the actual offering, as well as any current or anticipated risks related to the business.

Information around licensing agreements, shareholders' equity, underlying patents, and proxy disclosures on directors and officers collectively constituted another significant portion of SEC scrutiny, followed by various other comments targeting company-specific accounting and regulatory features. Other recurring comments include those related to emerging growth companies, controls and procedures, revenue recognition, and material contracts.

The following infographic depicts a breakdown of the total 1,236 comments analyzed according to category and frequency.

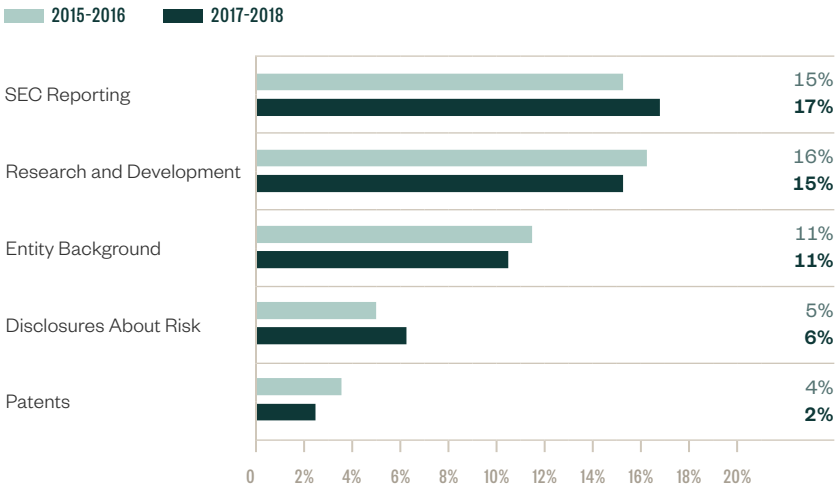
FIGURE 2: Overview of SEC Comment Categories
S-1, 10-K, 10-Q, & 20-F Filings, 2018–2019 (%)



SIGNIFICANT SHIFTS

A number of topics saw a slight-to-significant shift in focus when compared to 2017 and 2018 with the positive or negative variance measured as a ratio to the total number of comments. This included categories such as SEC Reporting, or process compliance, risk-based disclosures, patents, entity-related information, and R&D.

FIGURE 3: Significant Shifts in SEC Focus for Overall Filings—By Ratio of Comments
S-1, 10-K, 10-Q, & 20-F Filings, 2017–2018 & 2018–2019 (%)



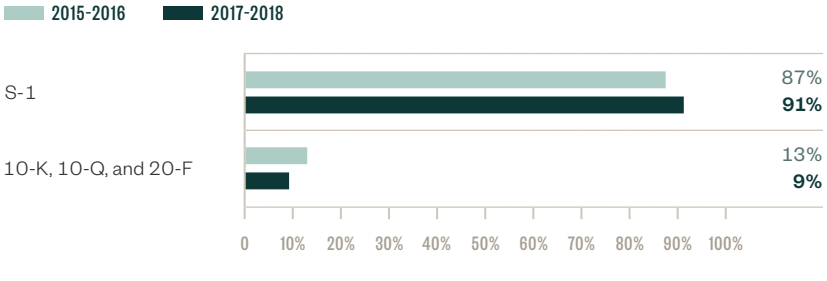
Comments related to SEC Reporting and risk disclosure saw an increase in focus by 1.5% and 1.2% respectively. Meanwhile, those directed toward patents, entity background, and R&D slightly declined by 1.1%, 1%, and 0.9% respectively.

Nevertheless, these shifts were relatively small in comparison to those seen in the 2017 and 2018 report highlighting that the nature and composition of comments over the last two years remained fairly intact.

BREAKUP–FILING TYPE

Similar to 2017 and 2018, S-1 filings continued to lead in relation to SEC scrutiny. Of the total 1,236 comments analyzed in this study, 1,126 comments—roughly 91%—were directed at S-1 filings, up from 87% in 2017 and 2018. Meanwhile, the remaining 9% spread out rather evenly among 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, 2017–2018 & 2018–2019

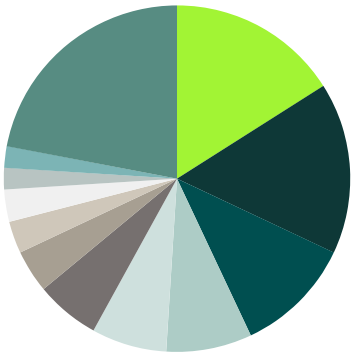


Trends in S-1 Filings

S-1 filings continued to be a primary focus for the SEC with 1,126 total comments—91% of the total 1,236 comments analyzed in this study. This is a slight increase from the 2017 and 2018 study when S-1 filings brought in 1,221 comments or 87% of the 1,401 comments analyzed in that report.

Topics such as R&D, SEC Reporting, or process compliance, and entity background generated the most attention in 2018 and 2019 garnering a share of 16.4%, 16.3%, and 10.8% respectively.

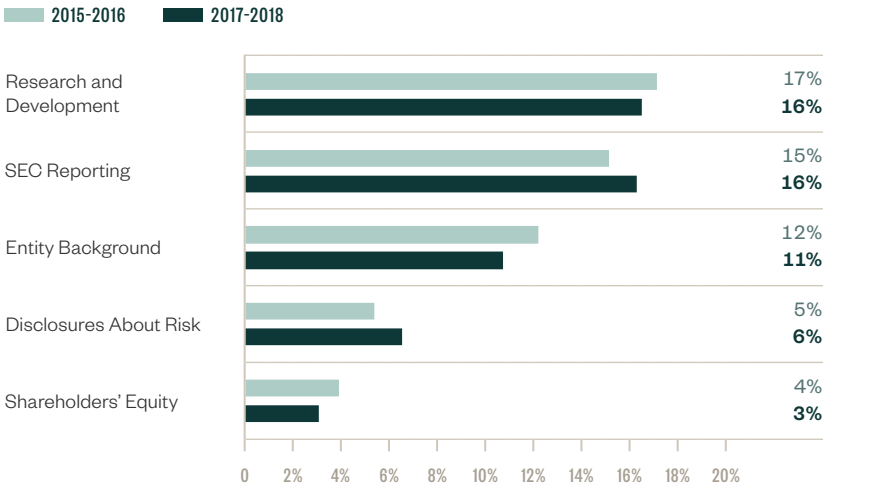
FIGURE 5: SEC Comments Categories for S-1 Filings
S-1 Filings, 2018–2019



16%	Research and Development
16%	SEC Reporting
11%	Entity Background
8%	Initial Public Offering
7%	Management's Discussion and Analysis
6%	Disclosures About Risk
4%	Licenses
3%	Shareholders' Equity
3%	Patents
2%	Material Contracts
2%	Disclosures About Directors and Officers
22%	Other Comments

1,126 Total Comments

FIGURE 6: Significant Shifts in SEC Focus for S-1 Filings—By Ratio of Comments
S-1 Filings, 2017–2018 & 2018–2019



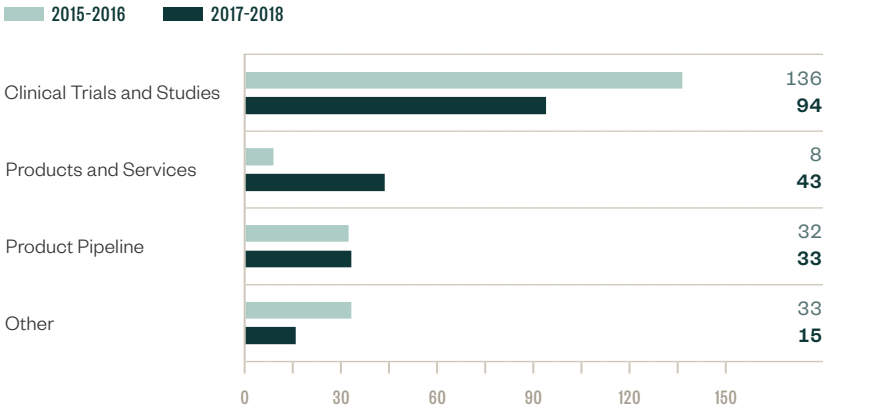
In our comparative analysis, we noted specific categories that made the greatest shift in relation to 2017 and 2018. For example, comments directed toward SEC Reporting and disclosures about risk increased by roughly 1%. Those comments under entity background, shareholders' equity, and R&D decreased by 1.4%, 0.8%, and 0.7% respectively.

These shifts were significantly smaller in comparison to the shifts seen in 2017 and 2018 when the percentage ranged from 3% to 5%.

The category composition mix remained largely intact over the last two years with certain salient topics continuing to attract greater SEC scrutiny. These key topics are examined in greater detail in the coming sections.

RESEARCH & DEVELOPMENT

FIGURE 7: Number of Comments—By Research & Development Subcategory
S-1 Filings, 2017–2018 & 2018–2019



R&D plays a critical role in the success of any business as it's a bedrock of creativity and innovation. For the life sciences industry, R&D lies at the heart of operational sustainability and competitive standing, driving both improvements in the current product portfolio and shaping the future pipeline.

The SEC's focus on R&D continues to stand strong year after year with the objective to understand registrants' research methodology, ongoing and planned trials, developmental pipeline, and key filings and communication with the FDA.

It's unsurprising that R&D continues to make up the largest category of comments directed at S-1 filings garnering a share of 16.4% in 2018 and 2019. While this is a slight decline from the 17.1% share witnessed in 2017 and 2018, the category's prominence for S-1 registrants remains intact.

Comments specifically related to clinical trials and studies, products and services, and the developmental pipeline constituted 50.8%, 23.2%, and 17.8% of the total number of R&D comments respectively.

As part of its modernization and simplification initiatives, the SEC modified Item 101 of Regulation S-K Description of Business, which took effect in May 2019. Companies are no longer required to disclose amounts spent on R&D activities in their discussion on business, given that a similar disclosure is already required pursuant to generally accepted accounting principles (GAAP).

However, the focus on R&D is still pivotal. As per the revised Item 101(a)(2)(iii)(B), registrants are required to provide, amongst others:

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

CLINICAL TRIALS AND STUDIES

Information and disclosure around companies' clinical trials and studies has consecutively encapsulated the largest share of R&D with a total of 94 comments making up a 50.8% share in 2018 and 2019. Comparatively, the number has dropped from 2017 and 2018 when there were 136 comments in this subcategory comprising 65.1% of total R&D comments.

The nature of focus has remained consistent in this area; companies are being required to disclose details including:

- Trial dates
- Location
- Scope and size
- Number of participants
- Dosage methodology and results, which includes all serious adverse events (SAEs) observed

They are also asked to provide product particularities—for example, the use of regulatory pathways or investigational new drug (IND) applications—that may alter the route of certain trials and include clarity on possible milestones that will be accomplished in the future.

The importance of completing sound clinical trials and studies isn't due solely to the huge amounts of time and costs involved. Clinical trials and studies are one of the most sensitive features of R&D that determine which product candidates make it to market. Companies must be transparent, provide exact research information, and give a balanced view of all their findings with each product candidate.

Sample Comments

> *We note the statement that you plan to initiate a Phase 2 clinical trial of [product name] for the treatment of [disease] in the first half of 2019. Please revise your disclosure to discuss any additional steps necessary to initiate such a trial, including the filing of an [investigational new drug] IND and any other material requirements you must satisfy.*

> *We note in your disclosure that you intend to pursue a Phase 2 clinical trial for [product name]. Please disclose how you will proceed to a Phase 2 trial, given it appears you haven't conducted any Phase 1 clinical trials, and disclose the regulatory pathway that you intend to pursue. Please expand your disclosure to discuss specific trial results for your product candidate on which you intend to rely, including the duration of the trial, the number of subjects or patients in such trials, how the drug candidate was administered, who conducted the trials, the dosage used, any serious adverse events experienced, the primary and secondary endpoints, and whether they were met.*

> *We note in your disclosure that no serious adverse events (SAEs) in your Phase 2 trial were assessed as definitely, probably, or possibly related to [product name]. Please expand your disclosure to include all SAEs, irrespective of whether the investigator determined such SAEs were treatment-related. Add similar disclosure where you discuss the safety results of your Phase 2b/3 clinical trial for the treatment of uremic pruritus on page 107.*

> *We note that the studies discussed in this section provide data without providing proper context for such data. For each of the studies discussed in this section, please disclose the date(s) of the studies, the sponsor and the location, scope and size, dosage and duration, and actual results observed, including any negative findings. Please also state whether you've published the data for any of your studies.*

PRODUCT-SPECIFIC INFORMATION

Apart from clinical trials and testing, there are a number of steps involved from the inception of a drug candidate to its final commercialization in the market. Information around these core value chain drivers—whether it be getting regulatory approval for the new drug in the target market, carrying out feasibility plans, or evaluating novel features of the product—remains another significant topic for the SEC.

Comments directed toward products currently in development constituted a 23.2% R&D share in 2018 and 2019, more than five times the amount in 2017 and 2018.

Many comments required registrants to provide greater disclosure on both the competitive advantages of a new drug or product-type, alongside any impending side-effects that are currently undergoing testing.

The SEC also requested companies to provide further discussion related to the following:

- Intellectual property
- Target indications
- Pre-clinical research
- Third-party relationships applicable to developing each drug candidate

The idea is to help investors get a transparent picture of all underlying aspects of a new product, which helps them make an informed opinion on its future market potential.

Sample Comments

> *Please clarify to what extent your efforts to develop [product name] for the treatment of [disease] are focused on the Japanese market, to what extent they are focused on the US market, and to what extent you may be targeting any other markets.*

> *We note that [product name] is being developed to treat tumors with [certain characteristics]. Here or elsewhere in your prospectus, please provide further details about the percentage or volume of tumors with [these characteristics], and any resulting impact on the potential commercialization opportunities for [product name]. Please also provide similar details for [product name] and [product name].*

> *Please balance the disclosure concerning current treatments to include the information that some of the user complaints, such as that the product is messy to use, could also apply to the topically applied drug you are developing. In addition, include the information, if true, that until clinical trials are completed, there is no data to support the belief that your product won't have side effects.*

> *We note your statements on page [X] and elsewhere in your document that based on a review of publicly available data on clinicaltrials.gov, you believe [product name] surpasses what other agents currently in clinical development for [disease] have demonstrated to date. Given that you haven't conducted head-to-head trials with the referenced agents, and the significant variables across clinical trials, it doesn't appear appropriate to make this comparison. Please delete this statement or tell us why you believe it's appropriate.*

DEVELOPMENTAL PRODUCT PIPELINE

Given the length of project incubation in the life sciences industry, having a clear understanding of the anticipatory developmental product pipeline is key. Investors should be well versed with a company's timeline for launching new candidates based on how well a product is progressing along the R&D spectrum.

SEC comments on the developmental product pipeline constituted 17.8% of total R&D comments in 2018 and 2019, maintaining its significance from 2017 and 2018.

The substance of scrutiny was still centered around pipeline tables; registrants were requested to remove programs that may be too early in the discovery phase. Companies are welcome to discuss more about their pre-clinical research in the body of their prospectus, but the actual pipeline table must only include concrete developmental candidates. Concurrently, the table must also prevent any misrepresentation and clearly display the various stages of development and dates where different candidates stand.

Sample Comments

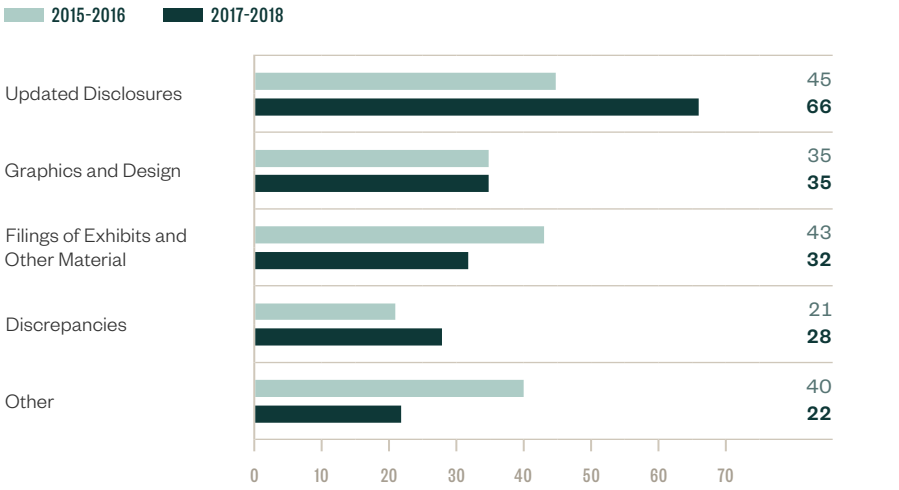
> *Please revise your pipeline table to remove the programs that are in the discovery phase. Because you haven't identified a product candidate for these programs, it's premature to include them in a product pipeline table.*

> *We note that your pipeline table includes the three preclinical programs that you are exploring and that you expect to file an IND application for at least one of these programs in the next 12 months. As your narrative disclosure only briefly discusses these programs, and they aren't otherwise discussed in the Summary section, please explain to us why you believe these programs are sufficiently material to your business to be included in your pipeline table.*

> *Please revise the pipeline table to replace the clinical development column in the graph with columns representing the clinical trials that will need to be completed prior to regulatory approval for each product candidate. Please also adjust the length of the arrows to reflect more precisely the current stage of development for each product candidate.*

SEC REPORTING

FIGURE 8: Number of Comments—By SEC Reporting Subcategory
S-1 Filings, 2017–2018 & 2018–2019



Comments related to SEC Reporting, or process compliance, are critically important for S-1 applicants who are going public for the first time. These registrants often end up with a large number of comments on their draft registration statements, and then are required to revise, add, or modify several sections of their prospectus and comply with requisite regulations.

On March 20, 2019, the SEC voted to adopt amendments to modernize and simplify disclosure requirements for public companies, investment advisers, and investment companies, which have been effective since May 2019.

These amendments include, amongst others:

- Simplifying the disclosure process through removal of repetitive disclosures and immaterial information and encouraging flexible reporting under MD&A on historical periods
- Improving the disclosure framework through elimination of risk factor examples and revision of the description of property requirement for materiality
- Updating rules through elimination of certain requirements for undertakings in registration statements
- Incorporating technology to improve access to information

Changes also allow registrants to omit confidential information from most exhibits without filing a confidential treatment request.

The amendments are consistent with the SEC's mandate under the Fixing America's Surface Transportation (FAST) Act, encouraging investor-friendliness by eliminating outdated and unnecessary disclosure.

This dynamic domain of process compliance remains pivotal year after year comprising 183 comments in 2018 and 2019. This was 16.3% of the total S-1 mix marking an increase from the 15.1% share witnessed in 2017 and 2018.

A host of subcategories within this larger sphere—the area around discrepancies, filing of exhibits, graphics, and updated disclosures—remained particularly important.

DISCREPANCIES

Given the length and breadth of a typical prospectus, the scope of discrepancies can be quite high. Companies are required to make varying disclosures in different sections of the document, which can lead to inconsistent facts, figures, or opinions. Topics range from the nature of clinical trials, products in development, corporate leadership, authorized shares outstanding, to extent of executive compensation and participation.

Focus on discrepancies constituted 15.3% of total process compliance comments in 2018 and 2019, up 33.3% from 2017 and 2018.

The SEC remains detail-oriented in its review of inconsistencies, requiring companies to revise even slight inferences or facts that may conflict with information provided in other areas of the prospectus. The entire document must be in sound agreement.

Sample Comments

> *We note that [officer name] is listed as an executive officer here who works on a part-time basis. However, in Exhibit 10.35, you indicate the possibility that [officer name] may not serve in any capacity and you may enter into a severance agreement with him. Please reconcile accordingly or advise.*

> *Please reconcile the inconsistencies between your disclosure here and the disclosure regarding your exclusive forum provision in the Choice of Forum section on page 154. Please note that we may have additional comments upon review of your revised disclosure and associated organizational documents.*

> *Please reconcile your disclosure here that you didn't provide any compensation to nonemployee directors with your disclosure on page [X] that you granted options to your non-employee directors.*

FILING OF EXHIBITS AND GRAPHIC DESIGN

Focus around filing requisite material as part of exhibits and graphics and design made up 67 of the 183 comments directed toward process compliance. This share represents approximately 36.6% of process compliance comments, slightly down from 42.4% in 2017 and 2018. However, the significance of these two categories remained intact.

Comments regarding filing of exhibits and graphic design were highly procedural in nature, requesting companies comply with all exhibit guidelines listed in Item 601 of Regulation S-K.

Going forward, while the SEC's amendments have reduced the disclosure of sensitive information to some extent, there are certain rules that are still applicable to first time filers. For example, contrary to amendments made in Item 601(b)(10), newly-reporting registrants are required to file material contracts entered into within two years of the applicable registration statement or report. Given such companies don't have previous filings on Electronic Data Gathering, Analysis and Retrieval (EDGAR), the provision of key information filed as exhibits is pivotal.

At the same time, companies must provide proofs of all graphics used in the prospectus, giving further disclosure, if required, by the SEC.

Sample Comments

> *Please file the lease agreement for your various leases as exhibits to your registration statement, or tell us in detail why you aren't required to do so. See Item 601(b)(10)(ii)(D) of Regulation S-K.*

> *Please revise your Exhibit 21.1 to identify the state or other jurisdiction of incorporation of each listed subsidiary and the names under which such subsidiaries do business. See Item 601(b)(21)(i) of Regulation S-K.*

> *Please provide us proofs of all graphics, visual, or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.*

UPDATED DISCLOSURES

All disclosures must be updated regularly given the nature of time-sensitive information in both the life sciences industry and the IPO market. This broad ambit of Updated Disclosures, as required by the SEC, went up by 46.7% in 2018 and 2019, compared to 2017 and 2018, constituting 66 comments or a 36.1% share of all process compliance comments.

The nature of disclosure ranged from updating financial statements, developmental assumptions, and company-specific websites. It also included detailing exclusive forum provisions, investors' rights agreements, and arbitration clauses, in addition to providing greater clarity on areas like sales of unregistered securities.

SEC scrutiny in this section is expected to continue. The most important factor for registrants is to keep information as up-to-date as possible in order to prevent recurring revisions.

Sample Comments

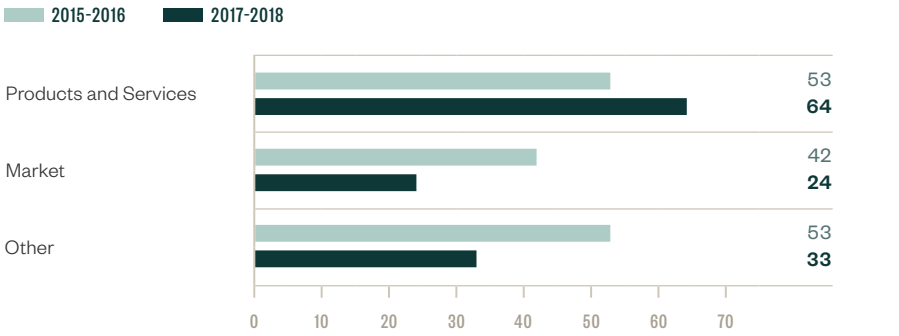
> *Please update your financial statements and related disclosures as required by Rule 8-08 of Regulation S-X.*

> *We note that certain of your disclosure appears to include dated information. For example, certain of your disclosures regarding regulations haven't been updated. Please revise accordingly.*

> *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 federal securities laws. Also ensure that the exclusive forum provision in your proposed organizational documents states this clearly. In this 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.*

ENTITY-RELATED INFORMATION

FIGURE 9: Number of Comments—By Entity-Related Information Subcategory
S-1 Filings, 2017–2018 & 2018–2019



The impetus on first-time filers to provide investors with a thorough background of their entity-wide operations remains critical. This background includes details regarding:

- External environment, for example competitive landscape, market potential, and size
- Internal product and services portfolio
- Organizational structure
- Regulatory ambit
- Collaborative arrangements, including those entered into with related parties and third parties

The intention is to help investors understand where the applicant stands in the market and gauge its internal framework and processes in order to deduce future performance.

Comments related to entity-related information made up roughly 10.8% of total S-1 comments in 2018 and 2019, slightly down from a 12.1% share in 2017 and 2018. The background information around products and services made up over 52.9% of the mix alone.

PRODUCTS AND SERVICES

A total of 64 comments were geared towards companies' products and services in 2018 and 2019—up 20.8% from 2017 and 2018. In terms of the content, the SEC continued to have registrants provide a more balanced disclosure of their existing product portfolio, which included disclosing their procurement, distribution plan, and cumulative sales.

Given that background information is one of the first sections in a prospectus, ensuring clarity and objectivity is key. Hence, many filers were required to define or explain certain terms of their corporate information, taking care to present their products in a way that a layman would understand. Any existing product description, or comparison with other products, must be backed by appropriate data such as:

- Target indication
- Approval from the FDA
- Representative class of customers
- Relative performance

The objective is to remove any superfluous statements and give a true picture of the firm's existing product and services base.

Sample Comments

> *Please significantly expand the description of your business operations in the summary and business sections. In doing so, please focus on your current operations. With respect to your planned operations, please be sure to clarify what your timeline is for pursuing those operations and what additional material steps or actions you need to take to pursue those operations. In addition, please address the following points:*
>
> - *Clarify what part of the marijuana plant your product is made from, such as leaves, hemp, other parts of the plant, or some combination of the above*
> - *Clarify whether you are conducting pre-clinical trials for any of your product candidates*
> - *Disclose if you grow marijuana or purchase it from suppliers and, if so, what are the locations of your operations*
> - *Who your suppliers are and if you have any supply agreements*
> - *How you price your products and what products you have in addition to [product name]*
> - *How you currently distribute your products and plan to price and distribute your products in the future*

> *Expand the description of the manufacturing of your product by [company name] to include information concerning the sources and availability of raw materials. Refer to Item 101(h)(4)(v) of Regulation S-K.*

> *Please revise your disclosure to briefly explain in terms a layman would understand, so they can understand what you mean when you say your product candidate is an "analog of an active metabolite" of an already approved drug. Please also disclose the drug that's already approved, when it was approved, the indication for which it was approved, and the fact that it was approved by the FDA as disclosed elsewhere in the prospectus.*

> *Please tell us the basis for your belief that your therapies constitute "the next generation" of therapies for patients suffering from cancer. In addition, please tell us the basis for your belief that your therapies will be "first-in-class."*

EXTERNAL ENVIRONMENT

While market-related comments declined by 42% in comparison to 2017 and 2018, they continued to be the second greatest subcategory in entity-related information, garnering a 19.8% share in 2018 and 2019. The SEC requested applicants to further clarify their addressable markets, including the basis for:

- Market size calculations
- Underlying assumptions
- Use of third-party studies
- Impact of material changes

One of the main objectives here is to ensure companies provide a balanced presentation of their business conditions, competitive landscape, and position in the industry. As filers, they're deemed liable for any third-party information they use to make market inferences when they provide details about how external forces can impact their organizational standing and product demand.

Sample Comments

> *We note your statement on page [X] asserting that you have a leading market presence in the [disease] disorder market outside the United States. Please disclose the basis for this statement. Please also expand your disclosures concerning the [disease] disorders market and the [disease] correction market sections to discuss the available treatment*

> *options outside the United States and the competitive landscape of these markets. Also revise your disclosure on page 5, as applicable, to clarify that your leadership position outside the United States relates to the [disease] disorder market.*

> *Your statements that you haven't independently verified third-party data, internal surveys, industry forecasts, and market research may imply an inappropriate disclaimer of responsibility with respect to the third-party information. You also state that forecasts are particularly likely to be inaccurate. Please either delete these statements or specifically state that you're liable for such information.*

> *Please tell us whether you commissioned any of the publications or studies cited in your prospectus.*

OTHER BUSINESS ACTIVITIES AND PRACTICES

Apart from the two core subcategories discussed above, a host of other factors made up the remainder of entity-related comments in 2018 and 2019. These ranged from areas requiring further disclosure on:

- Company's legal structure
- Applicable regulatory ambit
- Related parties
- Related party transactions
- Nature of collaborative activities across the value spectrum

The disclosure of related persons, promoters, and certain control persons stipulates from Item 404 of Regulation S-K.

Similar to the purpose of the entire entity background section, the objective is to help investors get a detailed overview on how the organization is structured and run and become familiar with all concerned stakeholders.

Sample Comments

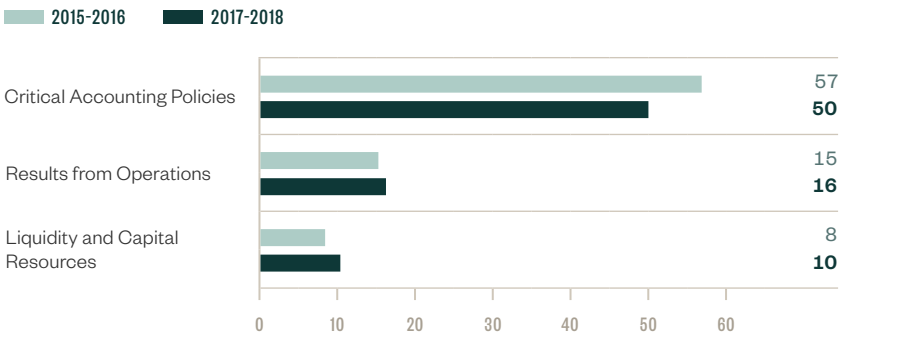
> *Your Business section doesn't contain discussion of the effect of existing or probable governmental regulation on your business. Accordingly, please revise to discuss the regulation of drug discovery and commercialization in US and Australia. Also revise to discuss US and Australian regulation of cannabinoid products.*

> *We note your disclosure that you are no longer a subsidiary of [company name]. Please expand your disclosure to explain your continuing relationship with [company name]. For example, we note that [company name] currently provides you with office space, certain administrative services, and equipment for no charge and that you share certain officers and directors with [company name].*

> *Tell us whether the participating doctors, who appear to be related to your CEO, received any compensation or any other benefit for their participation in this trial, and, if so, whether Regulation S-K Item 404 requires disclosure of their interest in the trial.*

MANAGEMENT'S DISCUSSION & ANALYSIS

FIGURE 10: Number of Comments—By Management's Discussion & Analysis Subcategory
S-1 Filings, 2017–2018 & 2018–2019



Item 303 of Regulation S-K specifically stipulates MD&A of the financial condition and results of operations which includes aspects such as:

- Liquidity
- Capital resources
- Operational results
- Off-balance sheet arrangements
- Contractual obligations
- Material changes
- Safe harbor

This area continues to remain a significant focus year over year aggregating 76 comments in 2018 and 2019—approximately 6.8% of total S-1 comments.

Given growing competition and volatility in global markets, maintaining information transparency is crucial. Companies are encouraged to be as detailed as possible when discussing their operational performance and pinpoint any material changes or uncertainties that can impact the business in the future. Cutting back on ambiguity is key for maintaining investor confidence.

CRITICAL ACCOUNTING POLICIES

Similar to 2017 and 2018, comments centered on critical accounting policies continued to lead in the MD&A sphere with a share of nearly 66% in 2018 and 2019. Majority applicants were asked to disclose differences between the fair value of their ordinary shares leading up to the IPO, and the estimated offering price, in order to clarify their accounting for equity issuance and stock compensation.

The SEC also required companies to clearly disclose their accounting policies in key business agreements, and explain any adjustments made to reconcile accounts with regulatory amendments.

Sample Comments

> *Once you have an estimated offering price or range, please explain the reasons for any differences between the recent valuations of your common stock leading up to the initial*

> *public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation.*

> *We note you make several adjustments in reconciling net loss to non-GAAP adjusted [earnings before interest, taxes, depreciation, and amortization] EBITDA measure. Please address the following: We note your adjustment to remove the step-up cost of the acquired inventory. Please explain to us in detail the adjustments, and tell us how you determined these adjustments are appropriate when they appear to result in individually tailored expense recognition methods. Refer to Question 100.04 of the Non-GAAP Compliance and Disclosure Interpretations issued on May 17, 2016. Please explain to us the royalty income adjustment and how you determined this adjustment is appropriate. Revise the description as necessary.*

> *It appears that you haven't included disclosure about your collaboration agreements in the notes to your financial statements. At a minimum, it appears that your agreements with [company name] and [company name] should be discussed. Please revise your financial statements as appropriate to disclose your accounting policy applicable to the elements of your collaboration agreements.*

RESULTS FROM OPERATIONS

A change in peak season or variation in product demand can lead to fluctuating performance throughout the year. This may not be easy to understand purely from financial statements where results could be viewed purely from a numbers perspective at a point in time. A discussion on operational results becomes important.

Comments directed toward results from operations constituted 21.1% of total MD&A comments, maintaining their significance from 2017 and 2018 and forming the second greatest subcategory of MD&A comments.

Companies were asked to explain factors such as:

- Specifics around changes in revenue throughout the year
- Nature of increases in certain expenses
- Modification or discontinuation of product lines

The objective is to clearly understand how the entity has been performing over time—not just from the bottom-line but through all its operational parameters.

Sample Comments

> *In your draft registration statement submitted [date], you reported net revenue and income from operations of [dollar amount] and [dollar amount] through the nine months ending September 30, 2017. Based on your results of operations for the full year of 2017, it appears that you generated [dollar amount] of revenue and [dollar amount] of income from operations during the fourth quarter of 2017. Please tell us the underlying reasons that resulted in your having generated approximately 46% of your revenue and 40% of your income from operations during the fourth quarter of 2017.*

> *Please revise the results of operations to discuss in greater detail the reasons for the changes in the various results of operations. For example, describe the reason for the increase in revenues for the period ended December 31, 2018 as compared to December 31, 2017. See Item 303(a)(3) of Regulation S-K and Section III.B.4 of SEC Release No. 33-8350 (December 29, 2003).*

> *Please quantify the amount of the increase in revenues attributable to changes in price and increases in volume. Also, provide the relative growth rate in revenue from sales of instruments versus consumables.*

LIQUIDITY AND CAPITAL RESOURCES

Item 303 specifically requires registrants to disclose any known trends, demands, commitments, events, or uncertainties that can impact their liquidity to indicate any material deficiency and course of remedy taken. Further, companies must also "describe internal and external sources of liquidity, and briefly discuss any material unused sources of liquid assets."

Comments related to liquidity and capital resources made up the remainder of MD&A capturing a share of 13.2% in 2018 and 2019. This marked a 25% increase in comparison to 2017 and 2018.

Applicants were asked to comment on their sufficiency of funds to continue running business for the next 12 months, both from the net proceeds of the offering along with current cash and cash equivalents. They were also asked to disclose any significant capital expenditure ahead.

Given the nature of the life sciences industry, a sound maintenance of funds is critical at all stages.

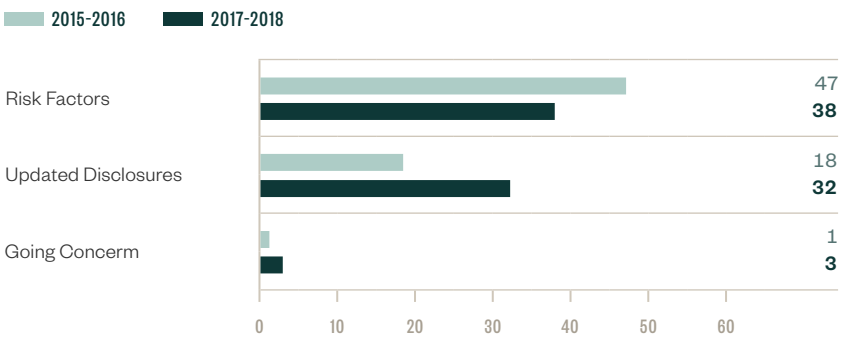
Sample Comments

> *Please revise to disclose your monthly burn rate and how long you anticipate your present capital will last at that rate. Please also disclose your current cash balance on hand as of the most recent practicable date and update that with any subsequent amendment. In this regard, we note your statement in the Use of Proceeds section on [page] that you expect the net proceeds of the offering, together with other sources of liquidity, to be sufficient to fund your operations for 12 to 18 months following the date of the prospectus. Explain the reasons that you believe the amounts disclosed are consistent.*

> *Given your regulatory approvals in other markets, disclose whether you will expend capital resources pursuing sales in those markets.*

RISK DISCLOSURES

FIGURE 11: Number of Comments—By Risk Disclosures Subcategory
S-1 Filings, 2017–2018 & 2018–2019



The life sciences industry has always grappled with balancing the amount of time needed to effectively roll out a new drug in the market versus becoming obsolete due to constant innovation. This dilemma has become even more prevalent during the COVID-19 pandemic; companies across the world are racing to find vaccines and treatments. Costs are high and time is limited. This builds up both risks and

opportunities in terms of keeping pace amidst an uncertain and pressurized environment.

Coupled with firm-specific characteristics—such as a distinct business model, processes, offerings, and standing—and each organization will end up having a portfolio of customized risks that are unique to its operations.

Disclosures about risk, both short-term and long-term, are pivotal in order for all stakeholders to make informed opinions.

While the discussion of risk factors was previously required in Item 503c of Regulation S-K, this has been effectively relocated to Item 105 post-modernization amendments. Companies continue to carry out a discussion of the "most significant factors that make an investment in the registrant or offering speculative or risky" under the risk factors caption.

The SEC continues to emphasize the discussion of significant risks, as opposed to generic risks, in order for registrants to be precise and concise. The final rule eliminates risk factor examples from the disclosure requirement, furthering a principles-based approach, and encourages the use of subcaptions for logical representation and coherency.

Risk-based disclosures continued to maintain their significance in 2018 and 2019 constituting a total of 73 comments, or roughly 6.5%, of total S-1 comments. This went up from the 5.4% share captured in 2017 and 2018.

Companies were asked to address risks related to issues such as:

- Regulatory restrictions and scrutiny over certain products
- Existing challenges in the R&D pipeline
- Intellectual property
- Collaborative arrangements
- Corporate governance
- Funding trajectory
- Liquidity constraints

They were also asked to update certain disclosures and reduce ambiguity in order to be more precise on exactly where the risks exist.

Sample Comments

> *Please add a risk factor discussing the legal limitations of your ability to protect your intellectual property due to federal and state laws prohibiting the production and sale of marijuana and related products.*

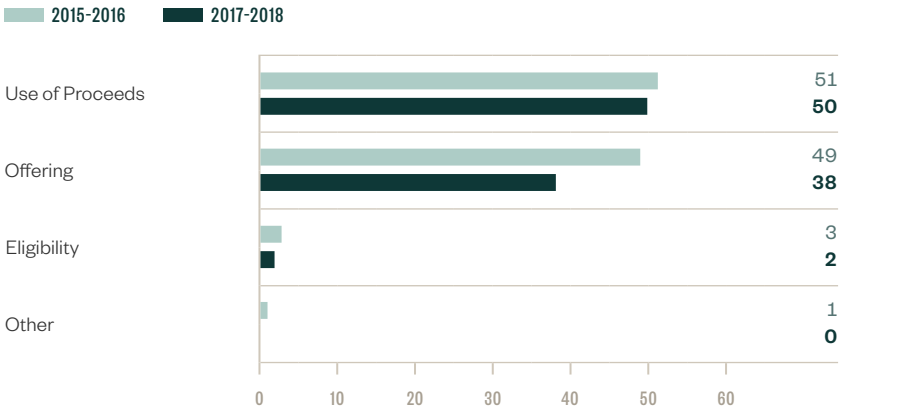
> *Please expand your risk factor to discuss the risk that concentration of ownership of your Class 1 common stock may prevent or delay a change of control of the company that shareholders may view as beneficial, as well as the risk that future issuances of Class 1 common stock may be dilutive to Class 2 shareholders.*

> *We note your disclosure in this risk factor that your drugs are in-licensed from other biotech or pharmaceutical companies and that you don't own the patents that underlie these licenses. Please specify the product candidates that you're referring to as well as the patents and the biotech or pharmaceutical companies from whom you have licensed such patents.*

> *We note your risk factor disclosure indicating that shortages of key raw materials may result in delays or the inability to meet demand. Please expand your disclosure to discuss the sources and availability of the raw materials for your product candidates including the strain of virus you use. Refer to Item 101(h)(4)(v) of Regulation S-K.*

IPO-RELATED DISCLOSURES

FIGURE 12: Number of Comments—By IPO-Related Disclosures Subcategory
S-1 Filings, 2017–2018 & 2018–2019



A total of 90 comments in IPO-related disclosures made up approximately 8% of total S-1 comments in 2018 and 2019—slightly down from the 8.5% share in 2017 and 2018.

These disclosures continued to remain significant for S-1 registrants taking root from Item 501 and 504 of Regulation S-K alongside rules and regulations under the Securities Act.

The completion of all requisite elements ranged from:

- Adding in a table of contents to the prospectus
- Making the right elections
- Disclosing offering conditions and its end date
- Making relevant judgments about the market price of common stock

Similar to 2017 and 2018, companies were also required to disclose their allocation of proceeds from the offering pursuant to Item 504.

OFFERING

SEC scrutiny around the actual offering comprised 38 total comments in 2018 and 2019 comprising 42.2% of the total IPO mix.

As stipulated in Item 501 and 502 of Regulation S-K, applicants were generally asked to revise their prospectus with details on the offering timeline, price of securities, the relevant market and underwriter obligations.

For those who had shares quoted on the OTC Pink Market, the SEC required them to disclose a fixed price at which their shares will be sold until the time they're listed on a national securities exchange or quoted on the OTC Bulletin Board, OTCQX, or OTCQB. Registrants who intended to have shares listed on specific markets were asked to disclose that there's no guarantee for their listing to be approved, and explain whether the offering is contingent upon such listing.

Concurrently, some companies were asked to refer to the Securities Act Rules Compliance and Disclosure Interpretations in terms of being clear with the number of common units to be offered or allocating the correct registration fee.

Sample Comments

> *We note your disclosure on pages 3, 18, 46, 65, and 94 that indicates you intend to have your shares quoted on the OTCQB. Please revise to disclose the eligibility requirements to have your shares quoted on the OTCQB, and clarify that there's no guarantee your shares will be quoted on the OTCQB. In addition, disclose here and on page 49 the exercise date of the warrant, the number of shares outstanding after both the direct offering and the selling stockholder offering in the aggregate, and, on page 49, disclose the termination date of the offering.*

> *We note your disclosure that your common stock is quoted on the OTC Pink Sheet Market. Please revise here, and make corresponding changes elsewhere in the prospectus, to disclose a fixed price at which shares will be sold 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. See Item 501(b)(3) of Regulation S-K.*

> *We note your disclosure that the rights offering will expire on or about a certain date, and that you may extend the rights offering for additional periods in your sole discretion. Please revise your disclosure to provide an expiration date for the rights offering that isn't indefinite. Refer to Item 501(b)(8)(iii) of Regulation S-K.*

USE OF PROCEEDS

Similar to 2017 and 2018, the use of proceeds subcategory remained dominant, making up a share of 55.6% of total IPO-related comments in 2018 and 2019. The SEC sought information related to Instruction 3 of Item 504.

Companies were asked to elaborate on how they intended to allocate the proceeds from the offering for their specified purposes, and quantify the breakup with corresponding milestones. They were also required to identify any other material funding needed to fulfill the desired purposes, and state the sources and amounts thereof.

The objective is to be as concrete and detailed as possible in explaining the use of proceeds of the offering, and cut back on uncertain outcomes and vague expectations.

Sample Comments

> *Please revise your use of proceeds section on page 25 to disclose a description of how you intend to use the proceeds received from the shares of common stock offered by the company, and how you intend to raise additional funds if the proceeds from this offering are insufficient to cover the intended uses. Your discussion should show the amount of proceeds to be allocated for each purpose, assuming different amounts of proceeds raised and the number of shares sold. To the extent that you intend to use the proceeds for the development of your product candidates, disclose an estimate of how far you expect to reach in the development process.*

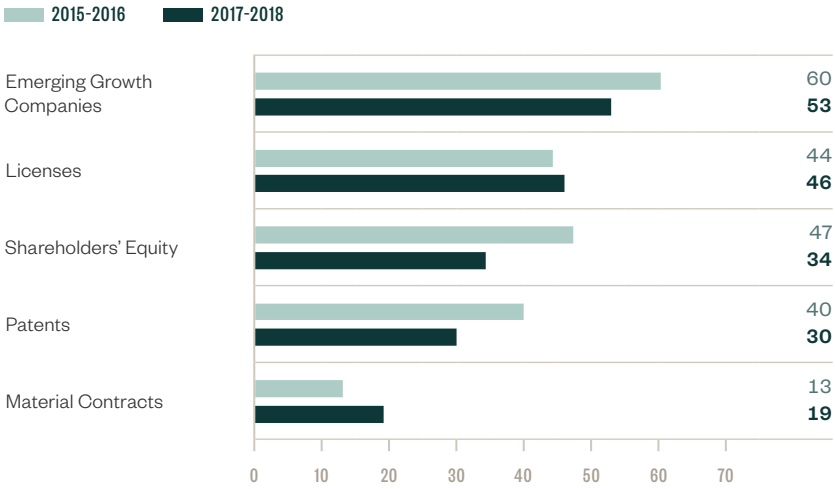
> *We note your disclosure that you intend to use net proceeds to fund the clinical development of [product name] and [product name]. Please specify how far in the development of each of the listed clinical trials you expect to reach with the proceeds of the offering. If any material amounts of other funds are necessary to accomplish the specified purposes, state the amounts and sources of other funds needed for each specified purpose. Refer to Instruction 3 to Item 504 of Regulation S-K.*

> *Please revise the discussion to identify the stage of development you expect to achieve for [product name], and each of your product candidates referenced in your second bullet point, with the proceeds of the offering. To the extent you expect to begin a*

particular stage of development but don't expect to complete it, please indicate that you will need to raise additional funding to complete that stage of development.

OTHER DISCLOSURE TOPICS

FIGURE 13: Number of Comments—Related to Other Disclosure Topics
S-1 Filings, 2017–2018 & 2018–2019



A wide range of other topics were covered in S-1 filings in 2018 and 2019 including comments directed toward:

- Emerging-growth companies
- Licensing agreements
- Shareholders' equity
- Patents
- Material contracts

Together, these topics comprised over 16% of total S-1 comments.

EMERGING GROWTH COMPANIES

The onset of the Jumpstart Our Business Startups (JOBS) Act in 2012 catalyzed the growth of small businesses, helping them go public under the emerging-growth company (EGC) status. This status enables them to make less expansive disclosures than required by non-EGC candidates.

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

- Its total annual gross revenues are $1.07 billion or more.
- More than $1 billion in non-convertible debt has been issued in the past three years.
- It becomes a large accelerated filer as defined in Exchange Act Rule 12b-2.

EGCs make up a variety of industries; pharmaceutical companies represent one of the largest groups of EGC IPO issuers.

A total of 53 comments were devoted to EGCs in 2018 and 2019, maintaining their significance as of 2017 and 2018. The SEC continued to ask registrants to provide

copies of all written communications, per Rule 405 of the Securities Act, and requested clarification of their EGC status.

Sample Comments

> *Please provide us with supplemental 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.*

> *We note your disclosure that you're an emerging growth company. Please update the cover page to indicate that you're an emerging growth company and update your disclosure to clarify when you will cease to be an emerging growth company.*

LICENSES

Focus on license agreements comprised 4.1% of total S-1 comments in 2018 and 2019, up from 3.6% in 2017 and 2018.

Similar to the previous study, the SEC continued to emphasize thorough disclosures of the material terms of license agreements which include details such as:

- Parties' rights and obligations
- Agreement duration
- Royalty range
- Termination circumstances
- Payment provisions

Many companies were asked to further elaborate upon intellectual property involved in each licensing agreement including any third-party rights or implications. This also included being more precise with the receipt or payment of royalties.

Sample Comments

> *Your disclosure on page 139 indicates that royalties under the Amended [institute name] Agreement are payable on a product-by-product basis until expiration of the last-to-expire claim of a licensed patent that covers such product. Please revise to disclose the relevant expiration date for the last-to-expire patent.*

> *We note your disclosure regarding your clinical trial and license agreement with [entity name] and [entity name], pursuant to which you are entitled to receive revenue sharing of a "mid to high double-digit percentage of the net revenue." Please revise your disclosure to present a range of not more than 10 percentage points.*

> *Please disclose the material terms of the license agreement(s) for the '[number] Patent with [institute name] including:*
>
> - *Each party's rights and obligations*
> - *Duration of agreement and royalty term*
> - *Termination provisions*
> - *Payment provisions, including up-front payments, aggregate milestone payments, and royalty range*
>
> *We note that some terms of the 2012 license are provided on page F-14, but to the extent not disclosed, please revise your disclosure to include this information. In addition, please file the license agreement(s) as an exhibit to the registration statement, or tell us why this isn't required. See Item 601(b)(10) of Regulation S-K.*

SHAREHOLDERS' EQUITY

Comments directed toward shareholders' equity saw a moderate decline; they captured a share of roughly 3% of S-1 comments in 2018 and 2019 in comparison to a 3.9% share witnessed in 2017 and 2018.

Nevertheless, shareholders' equity continued to remain a significant topic. The SEC requested greater disclosure on the activities of:

- Selling shareholders
- Beneficial ownership
- Common stock value
- Possible dilution
- Nature of convertible preferred stock

For example, companies were often times asked to refer to Question 612.09 of the Securities Act Rules Compliance and Disclosure Interpretations in order to clarify whether their purported secondary offerings were in reality indirect primary offerings. This could change the nature of the required disclosure along with governing rules.

Many were asked to provide the full terms of their convertible stock—and the possible exercise of outstanding warrants and options—in order to gauge upon their impact on common stock outstanding including implications upon ownership and control.

Sample Comments

> *We note your disclosure on page 141 that, "Each share of Series B Preferred Stock in the table below will automatically convert into one share of our common stock immediately upon the completion of this offering." Please also disclose whether all outstanding Series B Preferred Stock will convert into common stock upon completion of the offering. Also discuss, as applicable, any terms of the conversion that are contingent upon the offering.*

> *We note the selling shareholders and certain affiliates of the selling shareholders previously registered the resale of shares underlying convertible notes on Form S-1. Please tell us whether the selling shareholders or their affiliates continue to resell shares under the prior Form S-1. If not, please tell us the amount of time that has passed since they have sold substantially all of the shares. In addition, please revise your disclosure in the current Form S-1 to provide a materially complete description of the relationship between the selling shareholders and the company within the past three years. Refer to Item 507 of Regulation S-K.*

> *Please expand to disclose how the amounts and percentages in the table on page 77 would change, assuming the exercise of all outstanding options and warrants. Include in these revisions the right to acquire common stock mentioned on page F-25.*

PATENTS

The focus on patents remained relatively consistent capturing a share of 2.7% of total S-1 comments in 2018 and 2019—a moderate decline from 2017 and 2018.

Similar to the previous study, the SEC continued its scrutiny on companies' patent portfolios, and required them to separate patents by product candidate and disclose details such as the nature of patent ownership, its type, jurisdiction, and expiration.

Further, companies were asked to broaden their discussion and touch upon all material patents pursuant to Item 101(c)(1)(iv) of Regulation S-K.

Given the criticality of securing intellectual property rights amidst intensified competition, the focus on patents will likely grow over time.

Sample Comments

> *Please revise your disclosure regarding your patent portfolio and separate by product candidate or procedure, drug formulation of the number of issued patents you have, whether the patents are licensed or owned, the type of patent, jurisdiction, and expiration date.*

> *Please revise your disclosure to discuss all of your material patents including the scope, relevant jurisdictions, and expiry dates. Refer to Item 101(c)(1)(iv) of Regulation S-K.*

> *Please revise to disclose the foreign jurisdictions in which you have issued or have pending patent applications, to which patent portfolios they relate, and expected expiration dates. Please also disclose expected expiration dates for any material pending US application. Additionally, we note your risk factor discussion on pages 50-51 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

Comments directed toward material contracts made up roughly 1.7% of total S-1 comments in 2018 and 2019—up from 1.1% in 2017 and 2018.

The SEC continued to scrutinize key agreements that companies have mentioned in their prospectus, requiring a thorough disclosure on their contractual terms such as:

- Rights and obligations
- Financial terms
- Payment obligations
- Termination provisions

This also included agreements with major suppliers and customers who ultimately could have a material impact on business operations.

Some companies were asked to provide more information on material research grants they received from various government institutions. They were required to clarify whether the government held any rights with regards to the products produced with the funds or instances which could disrupt or revoke the funding altogether.

Similarly, they were also asked to file any such material agreements as exhibits to the registration statement pursuant to Item 601(b)(10) of Regulation S-K.

The 2019 modernization amendments reduce the burden of reporting certain information that may be competitively sensitive, but they don't remove the onus on filers to disclose all information that's material to investors. Concurrently, the two-year look back test in the revised Item 601(b)(10)(i) still applies to newly-reporting registrants.

Collaborations are frequent in the life sciences space. Material contracts will always remain critical for investors because of their significance to business operations. Companies are thereby encouraged to clearly disclose such contracts in their filings appropriately.

Sample Comments

> *To the extent material, please disclose the materials transfer agreement, which you entered in October 2018, along with the material terms and conditions of such agreement.*

Your license agreement with [company name] and your asset purchase agreement with [company name] appear to be material contracts. Please expand your disclosure here, or in another appropriate section, to include all of the material terms of these agreements including financial terms and term and termination provisions.

We note your disclosure on page 66 that in 2018, you entered into a services agreement with a third-party to handle the manufacturing supply chain from drug substance synthesis through labeling and packaging for your planned clinical trials, and you may not be able to locate alternative suppliers. Please disclose the material terms of this agreement, and file it as an exhibit to the registration statement or tell us why you don't believe this is required. See Item 601(b)(10) of Regulation S-K.

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

The aggregate share of comments for Forms 10-K, 10-Q, and 20-F comprised 9% of the total 1,236 comments analyzed in 2018 and 2019—down from its share of 13% in 2017 and 2018.

Prominent topics within this included SEC Reporting, or process compliance, MD&A, and revenue recognition. Together, these topics made up 60 of the total 110 comments. Meanwhile, other topics included:

- Entity-related disclosures
- Internal control over financial reporting (ICFR)
- Disclosures about risk
- R&D

Unlike S-1 filings, comments related to current business operations, results, and accounting principles took an upper hand in relation to SEC scrutiny.

FIGURE 14: SEC Comments Categories for 10-K, 10-Q & 20-F Filings
10-K, 10-Q & 20-F Filings, 2018–2019

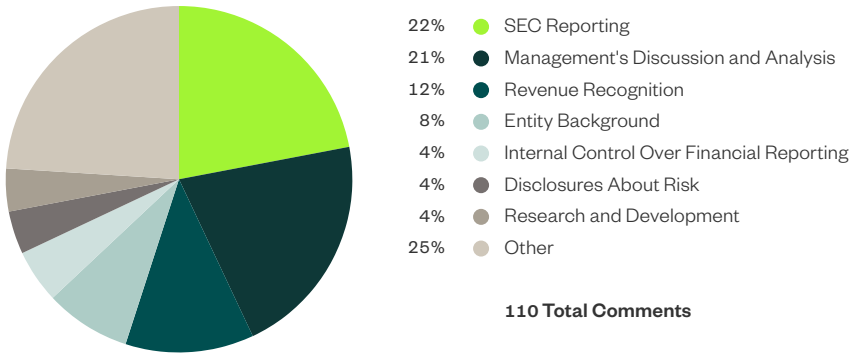
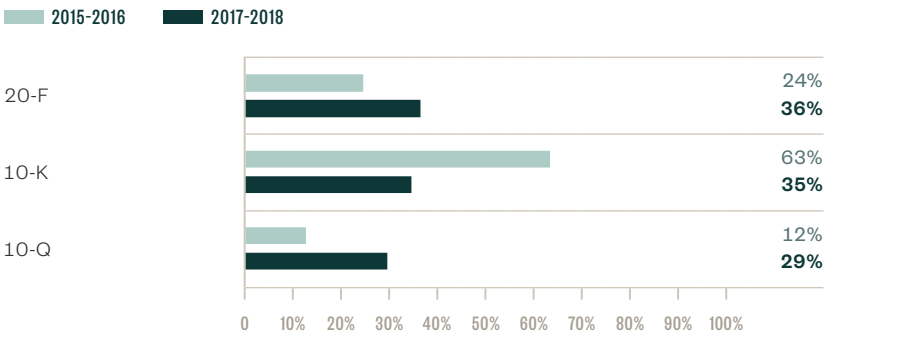


FIGURE 15: Ratio of Comments—By Filing Type
10-K, 10-Q & 20-F Filings, 2017–2018 & 2018–2019



Contrary to the previous study, the breakup of total 10-K, 10-Q, and 20-F comments—filing-type wise—was more balanced in 2018 and 2019. The dominance of 10-K dropped; comments were evenly divided between 10-K and 20-F filings at 35% and 36% respectively. Meanwhile, the share of comments directed at 10-Q also went up constituting 29% of the mix.

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, 2017–2018 & 2018–2019

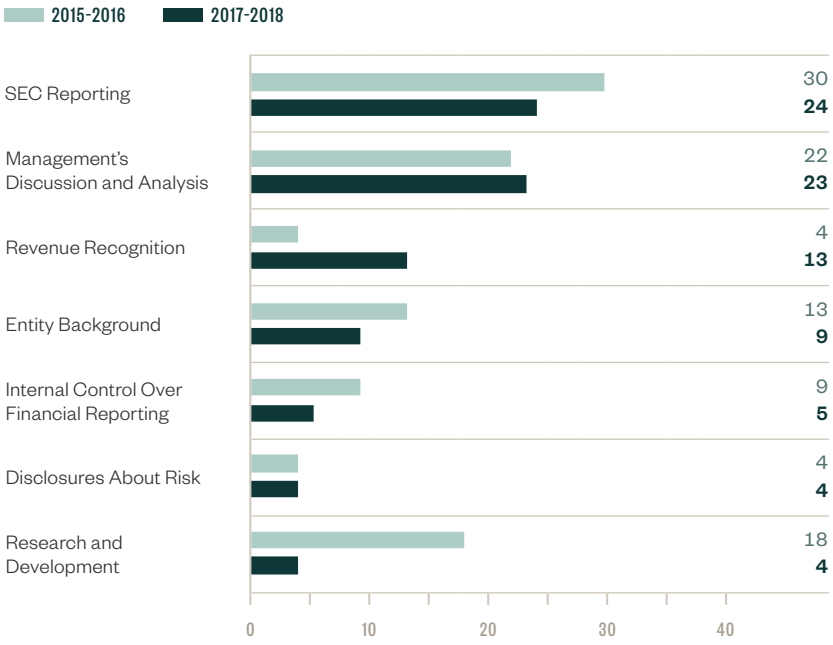
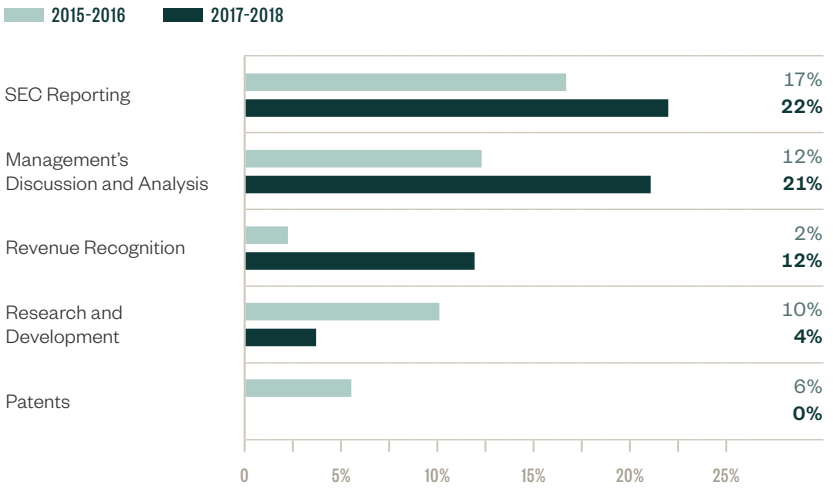


FIGURE 17: Significant Shifts in SEC Focus for 10-K, 10-Q & 20-F Filings—By Ratio of Comments
10-K, 10-Q & 20-F Filings, 2017–2018 & 2018–2019



In comparison to the previous study, the SEC placed much greater emphasis on revenue recognition and MD&A in 2018 and 2019; these categories increased by 9.6% and 8.7% respectively. Concurrently, comments related to SEC Reporting, or process compliance, also saw a steady increase of 5.2%.

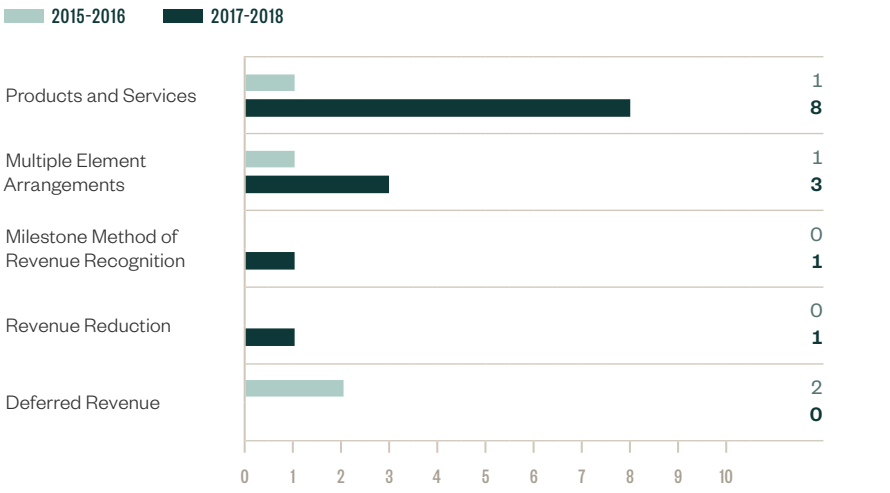
On the other hand, comments related to R&D received lesser attention and declined by 6.4%. There were no comments related to patents—a sharp decline in this category.

Nevertheless, these shifts shouldn't be misconstrued to say one topic is more important than another in SEC filings. For example, given the importance of intellectual property in the life sciences industry, a drop in patent-related comments doesn't mean they're insignificant. It could mean companies are making efforts for adequate disclosures and leaving little room for further scrutiny.

Keep in mind, this report is based on a certain time period with a finite sample size. Companies should refrain from drawing any generic conclusions.

REVENUE RECOGNITION

FIGURE 18: Number of Comments—By Revenue Recognition Subcategory
10-K, 10-Q & 20-F Filings, 2017–2018 & 2018–2019



Revenue and revenue recognition remain the most critical pillar in financial reporting given the complex nature of deliverables and timelines in every industry. The Financial Accounting Standards Board (FASB) issued Accounting Standards Codification (ASC) 606, Revenue from Contracts with Customers, in May 2014 with the intent to standardize key recognition policies and disclosures.

The standard became effective for public and private entities during annual reporting periods beginning after December 15, 2017, and December 15, 2018, respectively.

The core principle within ASC 606 is a company should recognize revenue when it transfers goods or services to a customer in an amount it expects to be entitled to receive for those goods or services.

One of the core objectives of ASC 606 has been to eliminate inconsistencies in how companies from different industries recognize revenue, encouraging comparability between statements.

Multiple element agreements predominate in the life sciences industry. Revenue payments are often broken down and linked with the completion of preset milestones which must be accounted for and presented transparently.

Comments in the revenue recognition section tripled from 2017 and 2018, constituting 11.8% of total post-IPO comments in 2018 and 2019.

The majority of the comments were related to companies' multiple element arrangements and required them to disclose exactly how and when certain

amounts of revenue became recognizable. Some of the performance obligations described were vague and left room for open-ended assumptions. The SEC required further clarification and had companies provide the methodology for determining and recognizing each performance obligation.

Certain recognition policies were also questioned, such as opting to recognize revenue upon the shipment of goods rather than upon delivery to the final customer. The SEC required companies to explain the rationale for their choice given the nature of products and the specific sale on hand.

The scrutiny related to revenue recognition, specifically ASC 606, is expected to continue until companies get settled with the standard.

Sample Comments

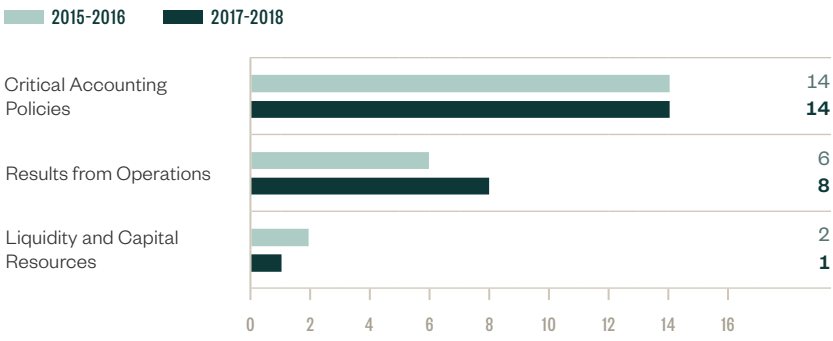
> *In the first full paragraph on page 10, you disclose if you're unable to reasonably estimate royalty revenue, or if you don't have access to the information, you record royalty revenue when the information needed for a reliable estimate becomes available. Please tell us how this policy complies with the requirement in ASC 606-10-55-65 to reflect royalties upon the later of subsequent sale, or the satisfaction of the performance obligation to which the royalty has been allocated. In your response, tell us when the information needed for a reliable estimate becomes available in comparison to the period of actual sale.*

> *Please describe and quantify for us the development, transition, and commercialization milestones under the [company name] collaboration not received as of June 30, 2018. Separately identify those you have included partially or fully in the transaction price and your rationale for inclusion.*

> *Regarding your disclosures for revenue from contracts with customers, in particular the [party name] agreement, please tell us your consideration of disclosing the following:*
>
> - *The aggregate amount of the transaction price allocated to the performance obligations that are unsatisfied and an explanation of when you expect to recognize revenue under the agreement. See ASC 606-10-50-13. It appears the company has two agreements with [party name], the license agreement and the supply agreement, which have different performance obligations. Tell us why you believe that the majority of the [amount] of consideration associated with the license agreement will be recognized as revenue as the company sells supply to [party name].*
> - *The significant judgments, and changes in judgments, made that affect the determination of the amount and timing of revenue recognition. See ASC 606-10-50-17.*
> - *The methodology used for determining the timing of satisfaction of performance obligations. See ASC 606-10-50-18 through 50-19.*
> - *The methods, inputs, and assumptions used for determining the transaction price and the amounts allocated to performance obligations, including your consideration of any constraints. See ASC 606-10-50-20.*
> - *Any practical expedients used under ASC 606-10-50-22.*

MANAGEMENT'S DISCUSSION & ANALYSIS

FIGURE 19: Number of Comments—By Management's Discussion & Analysis Subcategory
10-K, 10-Q & 20-F Filings, 2017–2018 & 2018–2019



The share of SEC comments on MD&A in total post-IPO comments increased from 12.2% in 2017 and 2018 to 20.9% in 2018 and 2019. The focus remained on companies' critical accounting policies followed by disclosures around operational results.

Inventory costing was one of key issues scrutinized during the time period of this report. The SEC requested clarity on whether inventory was reflected at the lower of cost or net realizable value. The implications of such on any subsequent inventory write-down, calculation of cost of sales, and derivation of margins was further sought.

The SEC also requested certain post-IPO filers reconcile operating results discussed in previous filings—for example, disclosures made in a previously filed Form 8-K versus those made in a current Form 10-Q—requesting coherency and detail across all aspects. This included discussing changes in operational results, quarter-to-quarter, alongside elaboration for the exact reasons for those changes and providing information on further trends.

In terms of the regulatory ambit, the 2019 SEC modernization amendments have further streamlined MD&A. When financial statements included in a filing cover three years, registrants are allowed to eliminate MD&A disclosure about the earliest year if they've already included such discussion in prior filings per revised instructions. At the same time, registrants have discretion to use any form of MD&A presentation that would enhance a reader's understanding without being limited to using year-to-year comparisons.

With these developments in mind, filers—similar to S-1 registrants—should be detailed, precise, and consistent in their discussion of operational results. Key policies used to account for transactions and processes must be duly explained with reference to authoritative literature.

Sample Comments

Regarding you accounts receivable at March 31, 2018, please provide us:

- *Description of the payment terms*
- *Amount considered past due as per your payment terms*
- *Amount due from each significant customer as well as the amount of revenue recognized from each during the three months ended March 31, 2018, and the year ended December 31, 2017*
- *Amount recorded for the allowance for doubtful accounts and the amount of bad debt expense recorded in your statements of operations for the three months ended March 31, 2018*

In your response, address your consideration for disclosing the above in your future filings.

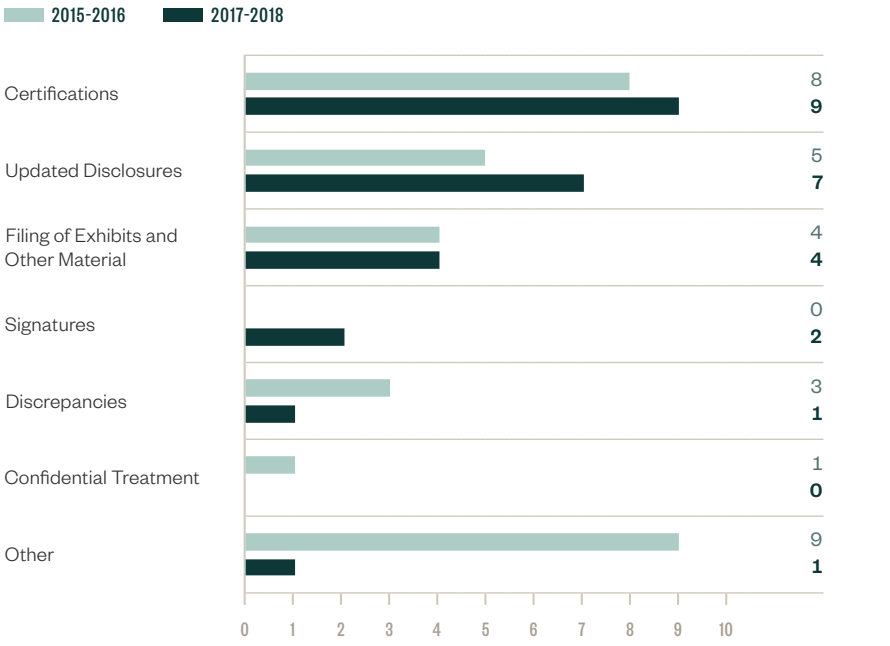
It appears you're presenting non-GAAP adjusted net loss and net loss per share as liquidity measures based on your statement that these measures remove the impact of stock-based compensation due to your emphasis on cash burn and, more specifically, cash used in operations. As such, please revise to provide a reconciliation of adjusted net loss to the most directly comparable GAAP measure for a liquidity measure, or cash flows from operations. In addition, please note that non-GAAP liquidity measures that measure cash generated must not be presented on a per share basis. Whether per share data is prohibited depends on whether the non-GAAP measure can be used as a liquidity measure, even if management presents it solely as a performance measure. Refer to Question 102.05 of the updated Non-GAAP Compliance and Disclosure Interpretation.

You disclose that inventory costs incurred prior to receipt of regulatory approval are charged to R&D costs when incurred. You also disclose here, and in comparable disclosure on page 8 of your September 30, 2018, Form 10-Q, that inventories on your period end balance sheets are comprised primarily of raw materials purchased subsequent to FDA approval of [product name]. Please tell us the following:

- *Dollar value of pre-approval inventory costs charged to R&D costs and the calendar years in which those costs were expensed*
- *Estimate of what cost of sales as a percentage of product revenue would have been for each quarter, from the third quarter of 2017 through the third quarter of 2018, if you hadn't charged pre-approval inventory costs to R&D expenses*
- *Estimated amount of future product revenue from sales of the zero-cost or low-cost inventory—for example, inventory that excludes costs charged to expense prior to regulatory approval—on hand at September 30, 2018, and the expected period of time over which it will be sold*

SEC REPORTING

FIGURE 20: Number of Comments—By SEC Reporting Subcategory
10-K, 10-Q & 20-F Filings, 2017–2018 & 2018–2019



Comments related to SEC Reporting, or process compliance, comprised 21.8% of the post-IPO mix in 2018 and 2019, up from 16.7% in the previous study.

Unlike S-1 filings, the major area of focus was on companies' certifications; comments in this subcategory increased 12.5% from 2017 and 2018. The SEC requested majority filers to provide new certifications in relation to internal controls over financial reporting (ICFR) in compliance with Item 601(b)(31) of Regulation S-K.

Updated disclosures was another significant subcategory. Companies were asked to update their financial statements or reconcile information-related disclosures made throughout the statement. Any deviation from procedural requirements had to be revised and backed by sufficient reasoning.

With a host of modernization amendments and updates making their way through the SEC sphere, the focus on process compliance is expected to continue.

Sample Comments

> *Please amend your filing to provide new certifications filed as Exhibits 31.1 and 31.2 to conform exactly to that provided in Item 601(b)(31) of Regulation S-K as it relates to ICFR. In this regard, the introductory sentence in paragraph 4 should refer to ICFR as defined in the Exchange Act and certification 4(b) and should discuss your obligations related to ICFR. Similarly, please amend the 10-Qs for the quarterly periods ended March 31, 2018, and June 30, 2018.*

> *We note that you only presented selected financial data for the years ended December 31, 2015, 2016, and 2017 instead of the required five most recent financial years, and you didn't explain the reasons for the omission in the filing. Tell us why you haven't provided*

> *five years of data and revise future filings to comply fully with Item 3(A) of Form 20-F and the related instructions.*

> *We note your risk factors on pages 9 and 10; please file, as exhibits to your registration statement, your agreements with the suppliers upon which your business is substantially dependent and the agreements governing your credit facility. Also, please tell us why you haven't included the agreements governing the 2018 private placement that you mention on page 81 and the consultancy and employment agreements mentioned on pages 93 and 94.*

OTHER DISCLOSURE TOPICS

ENTITY-RELATED INFORMATION

Disclosures on entity background comprised roughly 8.2% of total post-IPO comments—a slight increase from 2017 and 2018.

The discussion was largely focused on companies' regulatory environments, which included disclosing requisite clearances needed to market their products. Concurrently, some were asked to elaborate upon their operations in certain markets given that they may come under economic sanctions and export controls.

Sample Comments

> *We note your disclosure in the last paragraph that you have FDA approval through the 501(k) clearance path for [product name] and [product name]. Please tell us the basis for your conclusions that the 501(k) clearance means that the FDA has approved the products. Also, in an appropriate section of your document, please clarify whether the related services and accessories you mention on page 48 require additional clearance before you can market them in the relevant jurisdictions.*

> *In an appropriate section of your document, please address any material obligation to report to a regulatory body adverse events involving your products or services.*

INTERNAL CONTROL OVER FINANCIAL REPORTING (ICFR)

While comments related to ICFR almost halved in number when compared 2017 and 2018, they were still the fifth most significant category in 2018 and 2019.

The SEC clarified that certain companies fell under the purview of Item 308(a) of Regulation S-K given the passage of time that had elapsed since their initial statements. Hence, the companies were required to include management's report on ICFR including the assessment of the effectiveness of ICFR.

Sample Comments

> - *We note you filed an annual report for the prior fiscal year ended December 31, 2016, and the annual report for the fiscal year ended December 31, 2017, represents your second annual report since your registration statement on Form 10 went effective. As a result, pursuant to paragraph 1 of the Instructions to Item 308 of Regulation S-K, it appears you're required to comply with Item 308(a) of Regulation S-K. Please amend your Form 10K to include management's report on your ICFR, including management's assessment of the effectiveness of your ICFR as of December 31, 2017, as required by Item 308(a) of Regulation SK.*

> - *You disclose you haven't included a report of management's assessment regarding ICFR or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies. Please note, although you aren't required to have an attestation report done by*

> *your independent public accounting firm, you are required to include a report of management's assessment regarding ICFR in your Form 10-K due to the passage of time since your initial registration statement and the number of Form 10-Ks filed since that initial registration statement. Please revise by amending your Form 10-K for the year ended December 31, 2017, to include this report as required by Item 308 of Regulation S-K.*

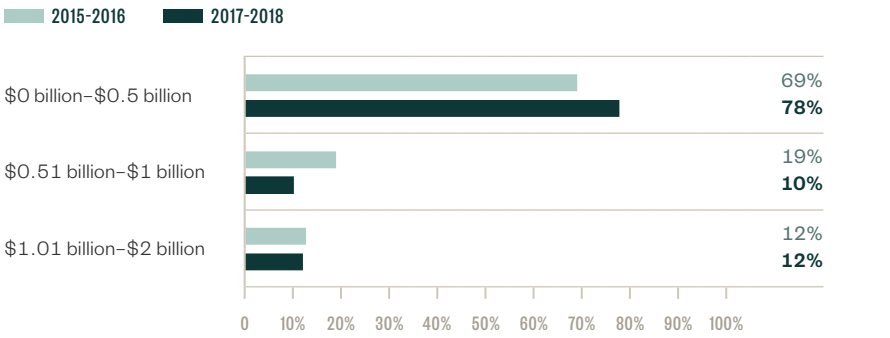
MARKET CAPITLIZATION RANGES

Per the methodology, the scope of this report focused on smaller companies with market capitalizations of less than $2 billion.

Over 78% of the SEC's comments were centered upon companies with market capitalization of up to $500 million. Consequently, 10% were directed toward those between $501 million to $1 billion, while 12% pertained to those greater than $1 billion but less than $2 billion.

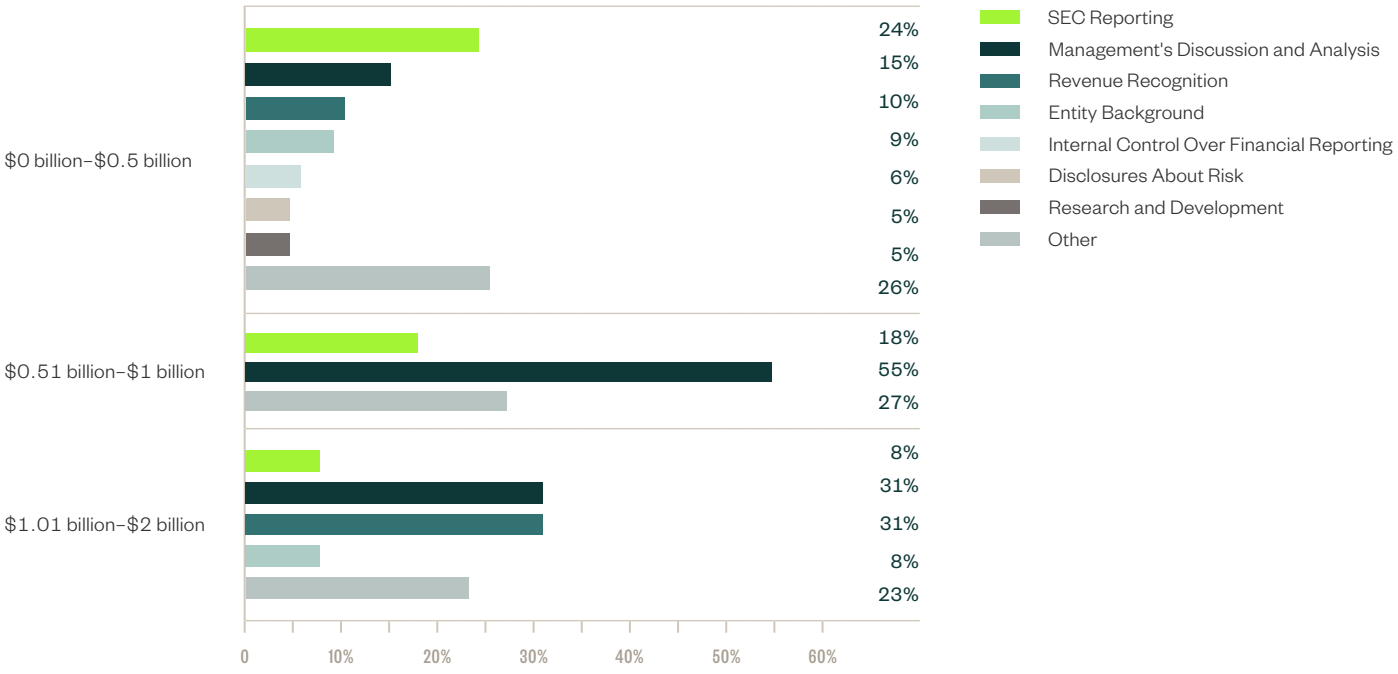
The trend of smaller companies attracting the greatest number of SEC comments continues year over year.

FIGURE 21: Ratio of Comments—By Market Capitlization Range
10-K, 10-Q & 20-F Filings, 2017–2018 & 2018–2019



In terms of the nature of comments, topics such as SEC Reporting, or process compliance, and MD&A were the focal points for smaller companies—almost 40% of the mix. This was then followed by other disclosure topics revolving around revenue recognition, entity background, ICFR, risks, and R&D.

FIGURE 22: Trends in Comment Categories—By Market Capitlization Range
10-K, 10-Q & 20-F Filings, 2018–2019



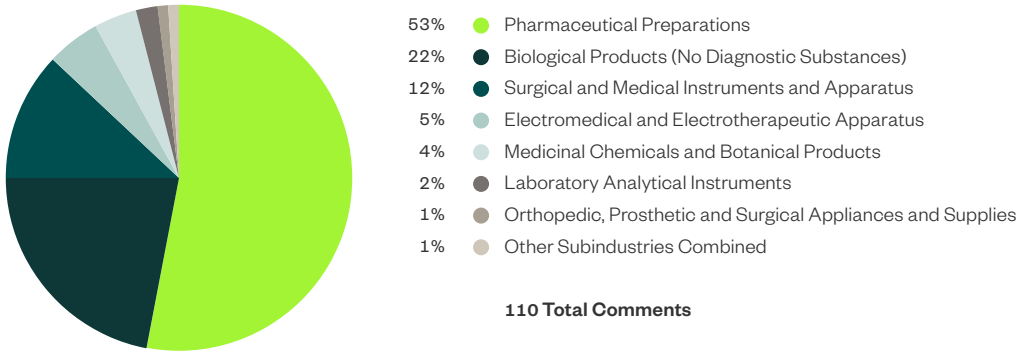
In contrast, larger companies didn't see much quantity or variety of comments. SEC scrutiny was mainly concentrated in topics such as SEC Reporting, MD&A, and revenue recognition. In contrast, larger companies didn't see much quantity or variety of comments. SEC scrutiny was mainly concentrated in topics such as SEC Reporting, MD&A, and revenue recognition.

This negative correlation between firm size and SEC scrutiny remains intact; the number of comments decreases as market capitalization increases. This could be attributed to experience and infrastructural setup. Companies that are less experienced in operations may not be as well-versed with procedural requirements and governance standards in comparison to their established counterparts. Larger companies tend to have more resources, in-house personnel, market experience, and are able to address intricate compliance checks.

The pattern of smaller companies receiving a greater share of SEC comments is expected to continue. The objective is to ensure all firms—regardless of their size or experience—provide a fair and true picture to investors.

Subindustry Trends

FIGURE 23: SEC Comments—By Subindustry
S-1, 10-K, 10-Q & 20-F Filings, 2018–2019



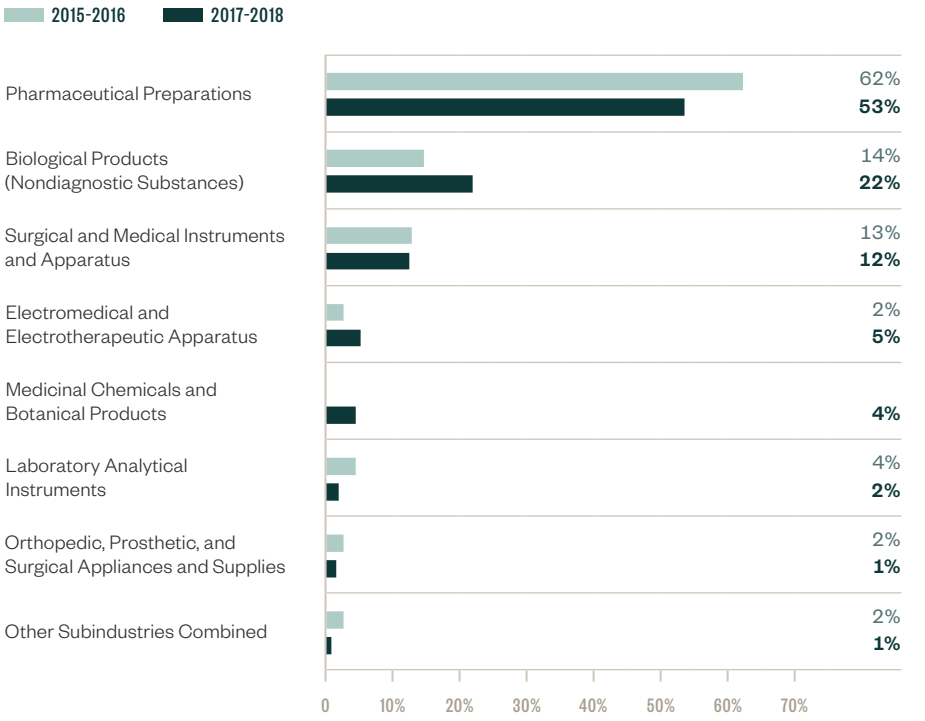
Of all the subindustries analyzed in this study, pharmaceutical preparations continued to get much of the SEC's focus. Its share of total comments fell from 62% in 2017 and 2018 to 53% in 2018 and 2019, but it still received much greater scrutiny in comparison to other subindustries. This is unsurprising, as the majority of the total S-1, 10-K, 10-Q, and 20-F filings made during the period under analysis were from companies in pharmaceutical preparations.

These companies generally are defined to be engaged in "manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use." This includes a wide product portfolio ranging from "ampoules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions." Given the range of this subindustry—along with its nature of research orientation and long gestation periods—the extent of compliance checks and disclosure can be substantial.

In terms of other subindustries, biological products stood as the next significant category with a share of 22%, followed by surgical and medical instruments and apparatus at 12%. The share of biological products increased substantially from the previous study by 7.2% with the total number of comments spiking 32%.

The breakdown of other subindustries was relatively small—below 5%. Meanwhile, medicinal chemicals and botanical products, which didn't attract any relevant comments in the previous study, garnered 54 SEC comments in 2018 and 2019.

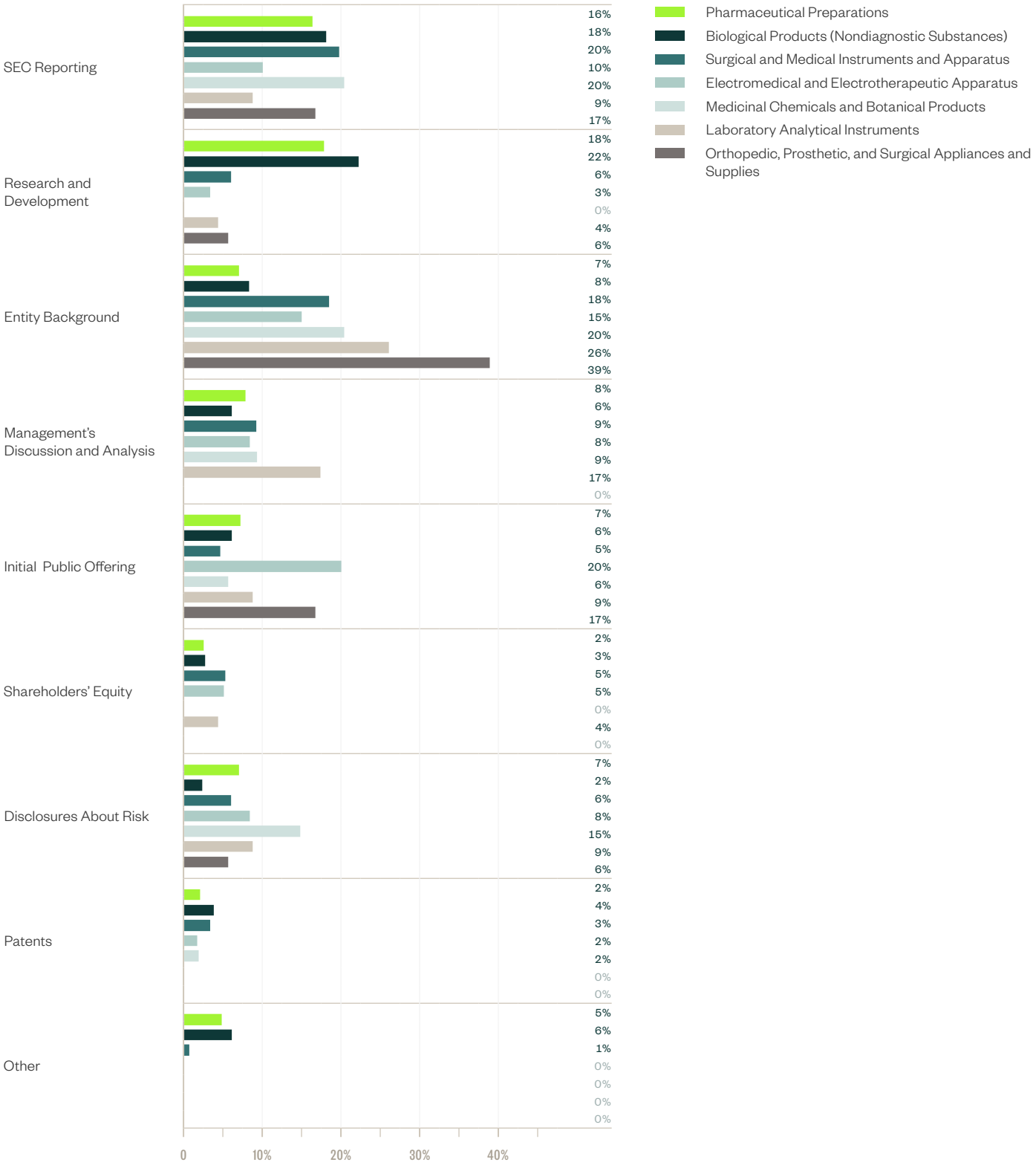
FIGURE 24: Significant Shifts in SEC Focus—By Subindustry
S-1, 10-K, 10-Q & 20-F Filings, 2017–2018 & 2018–2019



NATURE OF COMMENT CATEGORIES

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

FIGURE 25: Share of Comment Categories—By Subindustry
S-1, 10-K, 10-Q & 20-F Filings, 2017–2018 & 2018–2019



This trend was largely observed in the 2018 and 2019 report. For example, scrutiny related to SEC Reporting, or process compliance, was generically commonplace for the entire sector, especially companies in pharmaceutical preparations, biological products, and surgical and medical instruments and apparatus. Orthopedic, in addition to prosthetic and surgical appliances and supplies, saw a sudden spike in process compliance comments from 2017 and 2018 to 2018 and 2019.

The domain of R&D remained more significant for pharmaceutical preparations and biological products given the extent of developmental stake in these spaces.

Meanwhile, there remained a greater focus on entity-related disclosures for surgical and medical instruments and apparatus, laboratory analytical instruments, and electromedical and electrotherapeutic apparatus, ranging from 15-27%. Orthopedic, in addition to prosthetic and surgical appliances and supplies, saw a sudden increase in entity background scrutiny; disclosures were almost 40% of total comments. The SEC placed more onus on companies making adequate disclosures about their operations in the beginning of their statements given the complex nature of their product lines and the market studies involved.

The key takeaway is that while there may be some topics that remain common for the entire sector, the nature of others will continue to vary among subindustries. Filers need to stay abreast of the specificities of their own markets and pay close attention to any inherent challenges or sensitivities that may require additional clarification. It's important to identify and address these factors beforehand to prevent gray areas that can attract further scrutiny.

At the same time, the external environment isn't immune to changes. Macrodynamics, on both a local and global level, can also shift the SEC's focus toward certain key areas "of the moment" and further the scope of disclosures. Information clarity and transparency will remain critical at all points in time.

SECTION FIVE

Conclusion

Going public is a critical milestone for organizations, opening up new opportunities and avenues for growth. Concurrently, it also brings a greater number of responsibilities into the picture including:

- Generating timely audited financial reporting documents
- Maintaining sound investor relations
- Establishing governance oversight committees
- Staying up-to-the-mark with regulatory developments

COMPLIANCE TRACKER-SEC

Adherence to SEC standards is a crucial component in this regard, as it governs conformity from the very first IPO registration statement to all subsequent filings required in the public domain. Companies are always encouraged to create informatively sound documents, provide adequate disclosures on all critical matters, and keep investor confidence intact.

IMPLICATIONS ON LIFE SCIENCES

The trajectory of compliance parameters is further shaped by industry dynamics. The life sciences industry is undergoing constant change. Innovation stands at the forefront driven by extensive R&D. The COVID-19 pandemic has brought the industry to the brink of a major revolution. Competition is intense and stakes are high.

This sector-wide dynamism, coupled with regulatory developments, contoured the nature of SEC scrutiny in the 2018 and 2019 comment letter report.

FOCAL POINTS

Areas that received great attention were process compliance, R&D, and operational performance. Pre-IPO candidates were asked to expand on their clinical trials and studies and provide a fair picture of their products under development. This included:

- Details on the scope of their research studies
- Results observed,
- Regulatory approvals
- Current product pipeline reviews

Concurrently, these applicants were asked to comply with requisite procedural requirements, which ranged from reconciling discrepancies in statements and providing updated disclosures, to filing in relevant exhibits.

Focus on post-IPO filers was directed toward management's discussion of policies used to account for operations along with evaluation of financial results. Topics such as revenue recognition gained predominance given that many companies are getting familiar with the new accounting standards in place.

Meanwhile, entity-related disclosures remained a key topic for many companies, pre- or post-IPO, with the SEC requiring all companies to present a detailed and transparent background of their operations.

WHY IT MATTERS

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

This report aimed to familiarize life sciences companies with pertinent factors in their registration statements and filings, touching on the core SEC comments made. This applies to not only mid-cap companies included in the scope of this report, but all other current and future registrants.

Insights from these generic trends, coupled with guidance from specialist advisors, can help companies approach compliance in a thoughtful and thorough manner.

The Route Toward SEC Filing Information

FIGURE 26: The Route Toward SEC Filing Trends

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

WE'RE HERE TO HELP

To gain more insight into the SEC's comment process, or if you have questions about how to prepare your company for an IPO, contact your Moss Adams professional.

About Our Life Sciences Practice
We serve organizations of all sizes—from large multinational companies to middle-market corporations and start-ups, whether privately or publicly-held. 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 initial public offering. 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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