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Contingent Value Rights (CVRs) in Pharmaceutical Deals

Cleary Gottlieb Pharmaceutical, Biotech and Healthcare Group

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What are Contingent Value Rights?

Contingent Value Rights (**CVR**s) are used to provide additional value to stockholders of a target company upon the occurrence of specified future events.

CVRs are used regularly in pharmaceutical and biotech deals.

CVRs bridge the "value gap" attributable to uncertain future events that could change the valuation of a target business, sometimes drastically.

Most often seen types of CVRs include:

- **Event-driven CVRs**: payment triggered by a key event, often regulatory approvals for drugs, first commercial sale of a drug, etc.
- **Financial-driven CVRs**: payment based on sales of the target, often sales of a particular drug or a specific business line.
- **Litigation CVRs**: payment triggered by recovery (or sometimes absence of liability) from a key piece of litigation (e.g., a patent infringement suit)

CVRs allocate specific risks to offer additional deal certainty

BRIDGING VALUE GAPS	REPLACING CLOSING CONDITIONS	DEFERRED FINANCING
Where there are disagreements concerning valuation of an event, or an event is inherently speculative, a CVR can separate the event from the rest of the deal on which the parties have established an agreed valuation.	Where an acquirer might otherwise wish to wait on a drug approval or some other event as a closing condition, a CVR can replace that uncertainty with a contingent payment.	Because any payment associated with a CVR is delayed (sometimes by periods of 5-10 years or more), they can act as a type of deferred financing for a transaction.

CVRs allow an acquirer to purchase a target business and leave the risk and uncertainty of a future event with the target's stockholders.

… but CVRs are not without drawbacks

CVRs are not appropriate for all situations, and typically there must be some significant value in the potential event or contingency for them to be worthwhile.

There is **increased cost and complexity** with respect to negotiating and drafting CVR Agreements, particularly when the CVRs are intended to be listed on an exchange.

Litigation risk exists in any situation where the CVR is not paid out in full.

Covenants or other restrictions can limit the acquirer's business.

The CVR shifts **significant risk to the target's stockholders**, who, unless the CVR is listed, cannot generally cannot realize value for their rights until an event occurs and are subject not just to the risks of the event or contingency addressed by the CVR, but also to economic risks associated with the acquirers fortunes (e.g., bankruptcy).

Key Statistics

To better understand the CVR landscape, we analyzed all public transactions in the pharmaceutical and biotech industries since 2008 that included CVRs

36

Pharmaceutical/ biotech deals examined from 2008 to the end of 2020

6 Listed

Average deal size in equity value of **$16.3B** (median $3.3B)

30 Unlisted

Average deal size in equity value of **~$660M** (median $470M)

Of the deals that have either fully or partially paid out or have expired (24 total), only **1/3** have paid out to CVR holders and **6** of the **8** of these deals have only made partial payment (though some have the potential for additional payouts)

4%-64%

Percentage representing the total consideration offered in the underlying deals represented by CVRs (assuming milestones fully paid)

22.5% is the mean potential payout

Note: Information as of October 2021, with deals up to those announced in December 2020.

Approaches to Milestones

Pharmaceutical CVR Agreements have milestones that are based on the occurrence of certain events, the achievement of financial goals or a mixture of the two.

Of the deals in the survey, **20** had milestones based on events, **11** had milestones based on financials, and **5** had both.

These CVRs have an average of over **2** milestones per CVR, though may have as many as **6** milestones.

Event-based Milestones

Event-based CVR examples include:

— **Regulatory approval** is most common.

- Can include approval one or a set of regulators, including the FDA, EC and/or others.
- Instead of approval, milestones may be linked to notice (e.g., that a drug is "therapeutically equivalent" to another) or receipt of specific labeling.
- Payment may vary based on DEA scheduling (e.g., more if unscheduled, and lower payments if Schedule IV instead of V).

— **First commercial sale** after a drug is approved.

— Success or progress against **certain metrics in a clinical trial**.

— **Others**: achievement of production goals or a certain number of clinical treatment visits by patients.

Financials-based Milestones

Financials-based CVR examples include:

— **Achievement of a sales targets** during a certain measurement period, which triggers a fixed payment.

— **Variable payments equal to a portion of certain sales.** May be:

- fixed (e.g., pay 40% of net sales over a certain dollar threshold)
- progressive (2.5% of sales in a certain range, 5% of sales in a higher dollar range)

— **Others**:

- variable payments based on payments due under a license agreement
- EBITDA performance

Crafting Milestones: Crucial to Success

Milestones must be carefully crafted to be capture the intended outcome

OVERLY NARROW/SPECIFIC MILESTONES?

Case Study of SARcode Bioscience/Shire (2013)

— Shire purchased SARcode in 2013 for an upfront payment of $160M, with significant additional payments possible based on commercialization of Lifitegrast.

— The shareholder's representative sued for $425M in payments that it alleged had been triggered because the drug had been approved.

— The language of the milestone was contingent on certain endpoints being reached in a specific study, and because that particular study missed one of the endpoints, the Delaware court ruled that the milestones had not been triggered despite the fact that other studies demonstrated the endpoint in question and the drug was eventually approved.

- The milestone was too specific to cover the drug approval path taken which differed from expectations.

— Product ultimately sold to Novartis for $3.4B (plus $1.9B in potential milestone payments).

VAGUE MILESTONES?

Case Study of Gilead/Calistoga (2011)

— Gilead acquired Calistoga for upfront payment of $375 million and up to $225 million based on milestones.

— Shareholder representative asserted that a $50M milestone based on EC approval of a specified drug as a first-line treatment for a hematologic cancer indication was triggered.

— Court held meaning of "indication" to be ambiguous and context specific, requiring examination of parole evidence. Ultimately, determined parties intended term to be mean "disease", meaning milestone was not triggered based on EC approval of the drug only for a sub-population with a specified genetic mutation.

Listed and Unlisted CVRs

CVRs can be **tradeable** or **non-tradeable**.

— In our sample, all tradeable CVRs were also listed on an exchange.

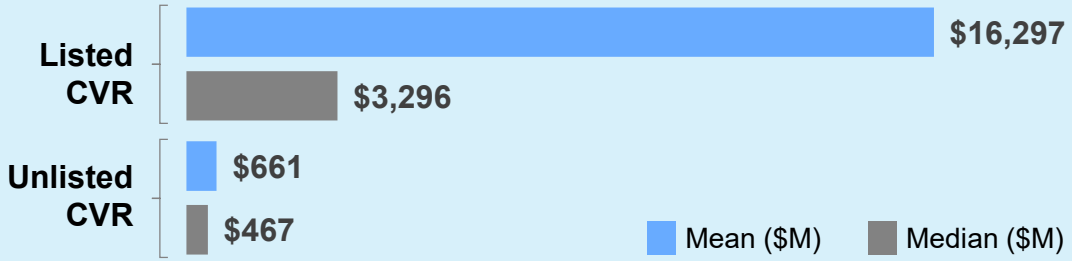
— Tradeable CVRs are required to be registered with the SEC, increasing complexity and costs.

< 20%

of the CVRs in the sample were tradeable

DEAL SIZE

Listed/tradeable involve significantly larger deals



MILESTONE TYPE

Listed CVRs are more likely to have both financial and event-driven milestones; of listed CVRs, 3 of 6 had both types, while only 2 of 30 unlisted had both

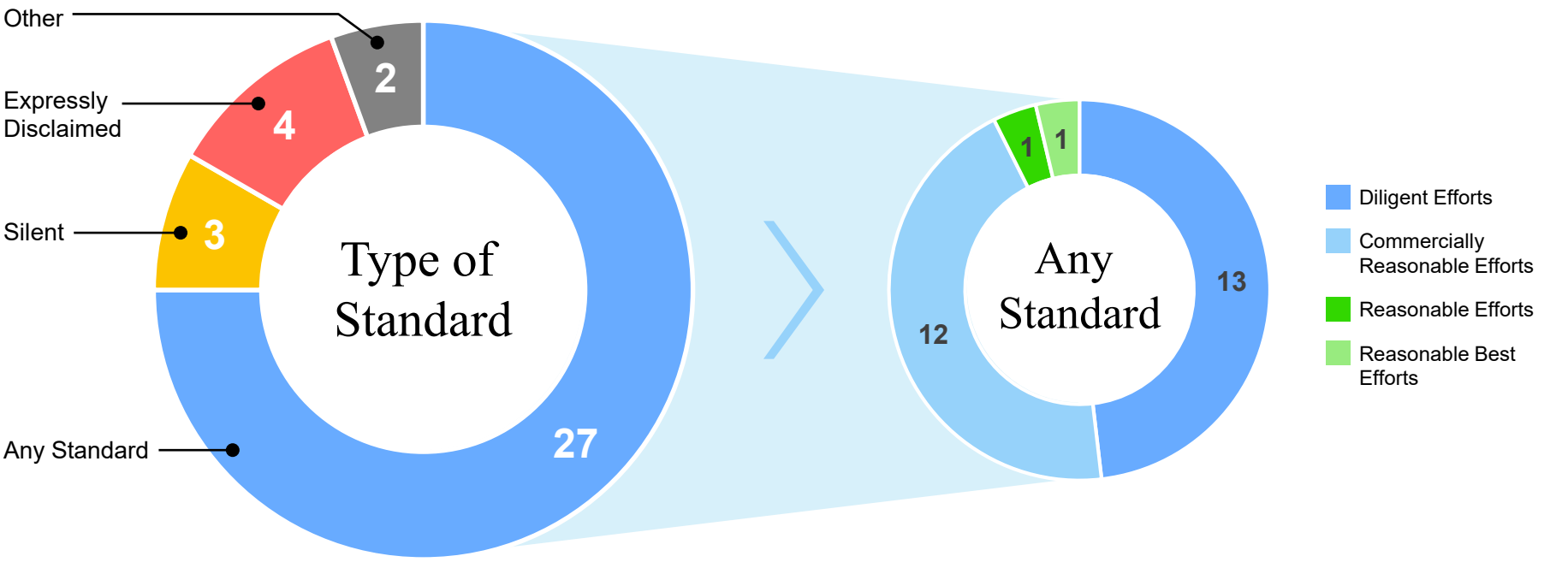
INCREASED LITIGATION RISK?

A third of listed CVRs in the sample have resulted in some litigation or investigation.

Efforts Standards

75% of examples contain a standard that mandates a certain level of effort that the acquirer must use in pursuit of the milestones.

25% are silent, expressly disclaim any effort required to meet the milestones or otherwise do not have a standard.



Considerations when Choosing an Efforts Standard

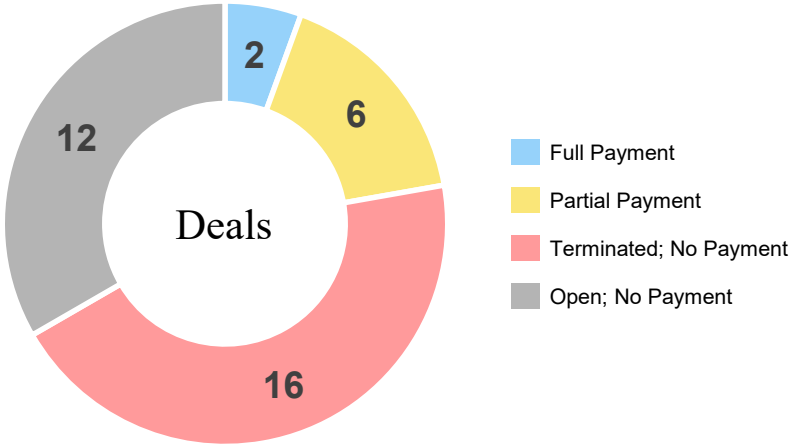
STANDARD	PROS	CONS
Efforts Standard	— Protection and value preservation for CVR holders — For an acquirer, may not be acceptable for a particular asset that it strongly desires to monetize	— Adds litigation risk in the event that the milestones are not met or are only partially met – CVR holders can argue that acquirer did not use require level of effort in pursuit of the milestones
Silence	— Lack of a standard may be easier and less costly to negotiate, particularly for an acquirer seeking to avoid an effort standard	— Court may find a standard was implied even if not expressly stated (and litigation risk may exist because of the ambiguity) — Less clarity for all parties concerning expectations
Expressly Disclaim	— Provides clarity that there are no specific expectations on future actions — For certain milestones, efforts standards may be unnecessary (e.g., financially-driven milestones shared between the parties may provide sufficient incentives) — Increases acquirer freedom to operate its business, particularly when prioritizing different drug candidates	— Less protection for CVR holders — Target will typically resist

Outcomes

CVRs are risky

Less than 50% of CVRs in the sample have resulted in any payout, and most of the payouts have been only a portion of the milestones

In our sample of 36 pharmaceutical CVRs:

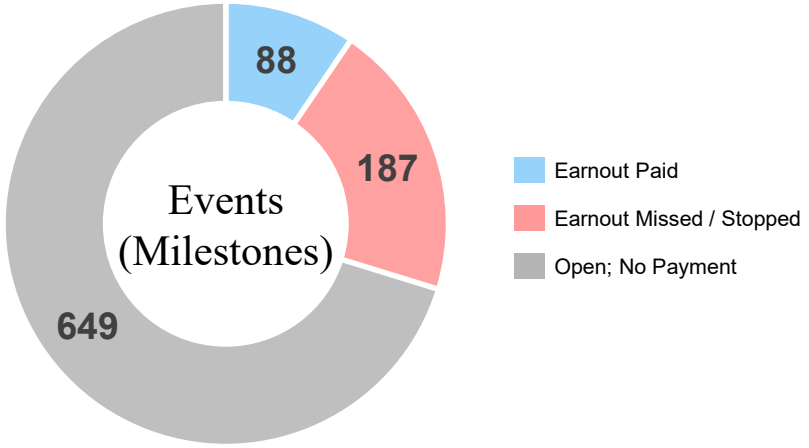


— Of the two full payments, one was based on drug approval and one was a reverse CVR (which paid out because a milestone failed)

— Partial payouts were based on regulatory milestones or partial achievement of sales milestones

• Deals with 3 or more milestones facilitate partial payouts

Private deal earnout data shows similar risk:



— In a study covering 107 deals with 924 possible earnout milestone events, approximately 10% had paid out, 20% were missed or the program had been stopped, with the rest pending

— Of milestones due in by mid-2021, about 34% had paid out versus the remainder that were missed or pending

Source: Private deal earnout data from SRS Acquiom, 2021 Life Science M&A Study.

Litigation

- Litigation risk exists in any situation where the CVR is not paid out in full.
- Cases involving CVRs have alleged claims for securities fraud or breach of contract.
- Although a number of cases involving CVRs have been dismissed, parties in some cases have settled after partial denials of motions to dismiss.

TONGUE V. SANOFI, 816 F.3D 199 (2D CIR. 2016)	*AM. STOCK V. SANOFI*, NO. 15-CV-8725 (S.D.N.Y. 2015)	*SMARTALK SECS. LITIG.*, 124 F. SUPP. 2D 487 (S.D. OHIO 2000)	*ROSSDEUTSCHER V. VIACOM*, 768 A.2D 8 (DEL. 2000)
Plaintiffs received CVRs based on FDA approval of drug. **Basis of Claims**: Securities fraud. **Result**: Claims dismissed because Sanofi had no obligation to disclose public information regarding FDA approval that tended to cut against their projections, particularly considering investor sophistication.	Plaintiffs received CVRs based on FDA approval of drug. **Basis of Claims**: Breach of contract. **Result**: After a motion to dismiss was granted in part and rejected in part, the parties proceeded to discovery. Before the court decided summary judgment, the parties settled in 2020 for $315 million.	As part of a stock-for-stock acquisition, plaintiffs received CVRs based on revenues generated over 5-year period. **Basis of Claims**: Securities fraud and negligent misrepresentation. **Result**: Claims dismissed because the value of the CVRs was speculative, even according to plaintiffs' own allegations.	CVRs inversely varied to price of stock were issued in connection with merger. **Basis of Claims**: Breach of contract and unjust enrichment. **Result**: Unjust enrichment claim dismissed on grounds that it was precluded by the contract. Breach of contract claim remanded after reversing dismissal based on statute of limitations. Parties ultimately settled for $14.25 million.

Other Typical Terms

REDEMPTION RIGHTS	— While some agreements are silent on redemption rights, most explicitly state that they do not limit the issuer's ability to redeem the CVRs. — When listed, redemption rights often need to be disclosed and are sometimes limited on price or only allowed when there are 50% CVRs outstanding.
ASSIGNMENT	— Nearly all CVR agreements permit assignment as long as the successor assumes the obligations of the CVR. — Some agreements continue to make the original issuer liable, and assignment is sometimes limited only to certain companies (e.g., top companies in the pharmaceutical industry or companies with clinical development capabilities).
AMENDMENT	— Certain technical amendments can be made without the consent of the CVR holders as long as not adverse to the CVR holders. — Other amendments require CVR holder approval (e.g., of 50% or 30% of holders); in some agreements, certain types of amendments require unanimous consent.
GOVERNING LAW	— Delaware law governs most agreements. — But, New York law governs most CVRs that are listed and registered.

Mechanics of CVRs

CVRs are created by a Contingent Value Rights Agreement, usually agreed in form at the time of the signing of the transaction and entered into as of the closing.

A rights agent is appointed to manage the CVRs, facilitate payments and act in certain circumstances for the holders of the CVRs.

The milestones (whether for events, financial performance or otherwise) for payment are outlined in detail and the payment mechanics and timelines are established.

CVR Agreements often contain covenants by the acquirer, which can include efforts standards that the acquirer must perform in fulfilling the milestones and limitations on assignment or transactions concerning the business or drug molecule/line.

Some Law: Are CVRs a Security?

Depending on their features, CVRs may be considered **securities**, requiring registration under U.S. Securities Act.

To avoid treatment as a security, according to a series of SEC no-action letters, the following factors must apply:

1. the rights must be an **integral part of the consideration to be received in transaction and granted pro-rata**;
2. the rights must **not represent any ownership or equity interest** or carry voting or dividend rights or bear a stated rate of interest;
3. the rights must be **non-transferable**, except by operation of law or by will or intestacy;
4. the rights must not be evidenced by any form of certificate or instrument; and
5. any amount ultimately paid to the **holders must not depend on the operating results** of the surviving company or any constituent company to the merger.

Are CVRs a Security?

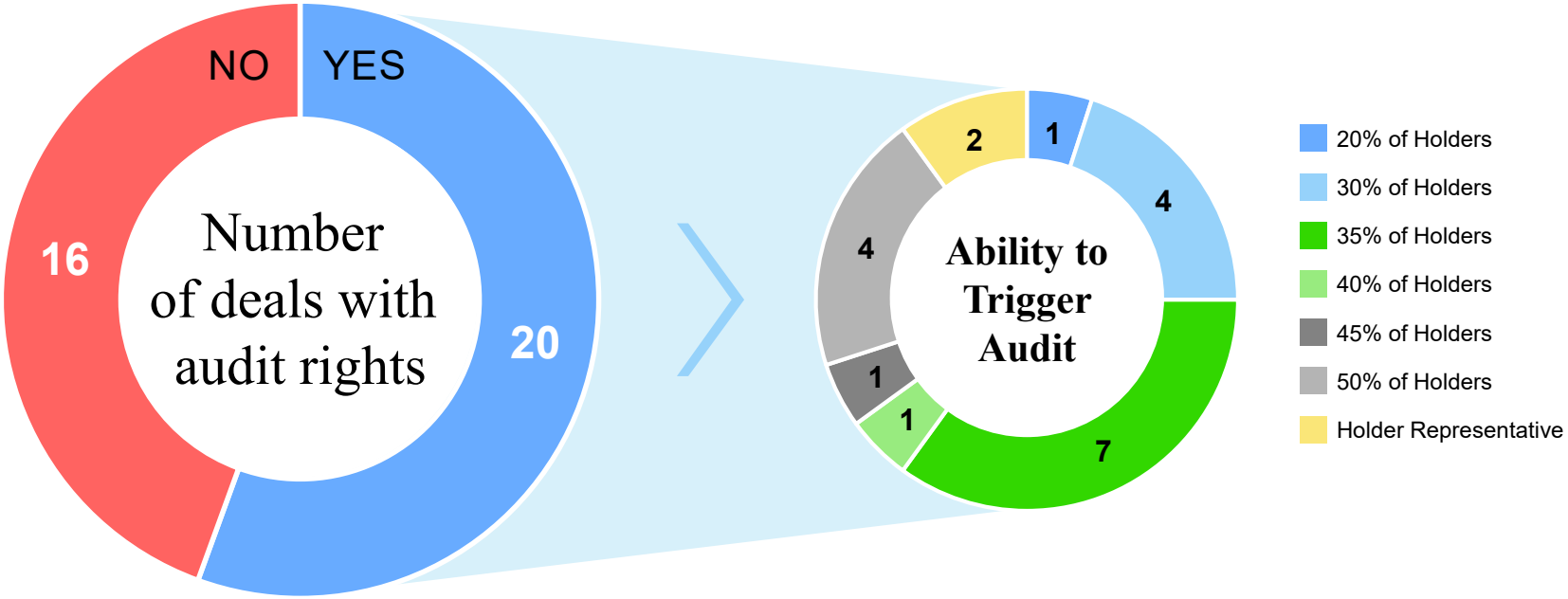
Transferability is the key feature determining whether a CVR will be treated as a security.

Though the staff has often provided no-action relief citing that a CVR is not dependent on operating results of a company, milestones are often structured to be dependent on a single product or some other narrower segment of sales:

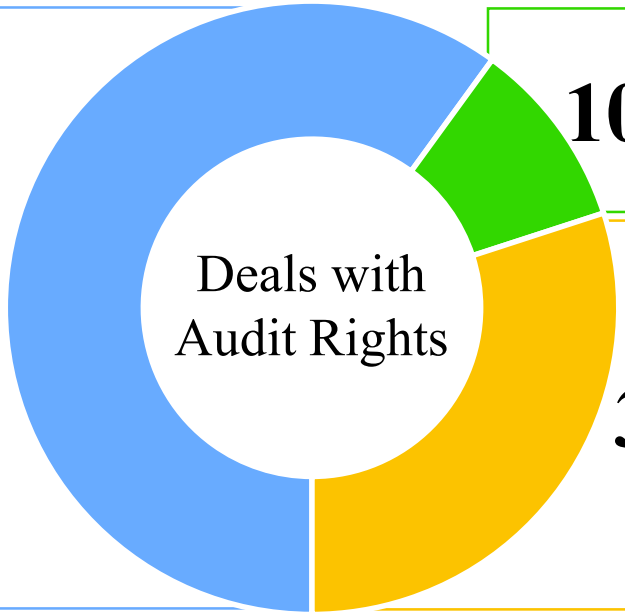
- In *Forest Laboratories/Clinical Data*, the company argued that their CVR "will not depend upon the general operating results of Forest, Parent or Purchaser, but will only relate to the net sales, if any, of the Product."
- Financial milestones such as (i) a percentage of sales of a particular product over a threshold or (ii) a fixed payment in the event a sales threshold of a particular product is reached are generally not deemed to be general "operating results."
- Registered CVRs have occasionally had milestones that would likely be prohibited for an unregistered CVR, such as EBITDA of a holdco containing the target company.

Audit Rights

- A majority of deals include an audit right, allowing an independent auditor (or in some cases, the holders or their agents generally) to verify the books and records underlying the acquiror's report on the milestones.
- Most frequently, action by 35% of the holders is required to trigger an audit, though there is significant variation in the sample



Audit Rights – Who bears the costs of an audit?



Company bears the fees charged by the independent accountant. **60%**

10% Acting Holders (holders who contested) bear the cost.

30% Distribution of costs contingent on audit findings (gained popularity in the past 7 years).

APPROACH 1	APPROACH 2
Company bears all costs if and only if the audit identifies a CVR payment shortfall or if the shortfall is greater than a certain threshold;	CVR holders and Company both bear the cost, based upon the percentage that the amount actually contested but not awarded to the holders or parent bears to the aggregate amount actually contested by the holder representative and parent.

Audit Rights – Other Terms

TIMING	— Audit requests must be submitted within a specified time window after delivery of statement confirming failure of milestones or the financials report.
FREQUENCY	— Generally, audit rights are available in connection with the determination of a milestone payment — When multiple audit rights are allowed, the frequency is expressly limited to a specific timeframe (e.g., once per year or once per milestone notice)
SCOPE	— 45% of deals limit the independent accountant's review to disputed items only.
REVIEW & COMMENT	— 20% of deals allow Acquiror and CVR holders to submit comments to the independent accountant's preliminary findings, which the independent accountant must take into consideration in good faith.
CONFIDENTIALITY	— All deals require entry into a confidentiality agreement.

Cleary Team Bios

Key contacts - Team Bios

Benet J. O'Reilly

Partner, New York

CONTACT INFORMATION

+1 212 225 2746
boreilly@cgsh.com

Benet J. O'Reilly's practice focuses on public and private mergers and acquisitions, private equity investments and restructuring transactions. He has significant experience across a broad array of industries, including pharmaceuticals and health care, technology and telecommunications. His notable experience includes:

- GSK in its acquisitions of Human Genome Sciences, Stiefel Laboratories, Reliant Pharmaceuticals and Genelabs, investments in Theravance, and sale of stake in ChemoCentryx to Vifor Pharma
- Viking Global Investors in its equity investments in Adaptive Biotech and Moderna
- CareCentrix in its sale to Walgreens
- RxHub in its merger with SureScripts

Kimberly R. Spoerri

Partner, New York

CONTACT INFORMATION

+1 212 225 2522
kspoerri@cgsh.com

Kimberly Spoerri's practice focuses on public and private mergers and acquisitions, private equity investments and corporate governance matters. Her notable experience in the pharmaceutical industry includes:

- Takeda in its $5.2 billion acquisition of ARIAD Pharmaceuticals and in its acquisition of the global rights to the development and commercialization of soticlestat
- Altaris Capital Partners in its acquisition of a 51% stake in Solesis
- Merck Sharpe Dohme in its JV with Sanofi Pasteur for the exploitation of hexavalent vaccine Vaxelis
- Allergan in its proposed $160 billion merger with Pfizer
- GSK in its acquisition of Human Genome Sciences
- Henry Schein in a Reverse Morris Trust transaction by which it spun-off its Animal Health business and merged it with a Clayton Dubilier & Rice portfolio company to form Covetrus

Jared Gerber

Partner, New York

CONTACT INFORMATION

+1 212 225 2507
jgerber@cgsh.com

Jared Gerber's practice focuses on complex commercial litigation, with a particular emphasis on securities litigation and other actions filed by shareholders. His notable experience includes:

- OPKO Health in a number of securities class actions and shareholder derivative actions concerning an alleged pump-and-dump scheme
- Allergan in a significant ruling denying class certification of securities class action concerning alleged misstatements concerning the safety of its breast implants
- MSD Animal Health in its $55 million acquisition of the rights for Vecoxan from Elanco Animal Health

Nallini Puri

Partner, London

CONTACT INFORMATION

+44 20 7614 2289
npuri@cgsh.com

Nallini Puri's practice focuses on corporate and financial transactions, including in particular, mergers and acquisitions, joint ventures and franchising. Her notable experience includes:

- Wockhardt Limited, the global pharmaceutical and biotechnology major, in its agreement with the UK government to fill finish COVID-19 vaccines for the United Kingdom

Timothy Saviola

Associate, New York

CONTACT INFORMATION

+1 212 225 2733
tsaviola@cgsh.com

Timothy Saviola's practice focuses on public and private mergers and acquisitions. His notable experience includes:

- International Flavors & Fragrances in its $45.4 billion merger with DuPont's Nutrition & Biosciences business via a Reverse Morris Trust transaction
- Warburg Pincus in its acquisition of Duravant, GA Foods and Infoblox

JD Colavecchio

Associate, New York

CONTACT INFORMATION

+1 212 225 2204
jdcolavecchio@cgsh.com

JD Colavecchio's practice focuses on litigation and enforcement matters. His notable experience includes:

- Keurig Green Mountain, Inc. in antitrust litigation filed by competitor alleging monopolization through exclusive dealing and predatory product design
- Defending suits brought by Fairfield Funds against certain HSBC entities