Biotechnology
Innovation
Organization

November 12, 2019

The Honorable David J. Kautter
Assistant Secretary (Tax Policy)
Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

The Honorable Charles P. Rettig
Commissioner
Internal Revenue Service
1111 Constitution Avenue, NW
Washington, DC 20224

The Honorable Michael J. Desmond
Chief Counsel
Internal Revenue Service
1111 Constitution Avenue, NW
Washington, DC 20224

Re: *Comments on Proposed Regulations § 1.382-7*

Dear Messrs. Kautter, Rettig and Desmond:

The Biotechnology Innovation Organization ("BIO") appreciates the opportunity to provide comments to the Treasury Department and Internal Revenue Service ("IRS") on proposed regulations under Section 382 with respect to the built-in gain and built-in loss rules of Section 382(h), as generally requested in the preamble to the proposed regulations.[1] Preamble to Prop. Reg. § 1.382-7, Fed. Reg. Vol. 84, No. 175B p. 47455 (September 10, 2019). The Preamble specifically requests comments on the proposal to eliminate the "Section 338 approach" permitted under interim IRS guidance providing safe harbors for the application of the Section 382(h) rules.

BIO represents 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 states. The biotech industry has created hundreds of thousands of well-paying jobs in the course of developing life-saving medicines and therapies. Many of these companies and organizations have been recognized as "best places to work." Because of the unique capital needs of biotech research, it often takes more than a decade and can take upwards of $2.5 billion to bring a single product to patients. The pharmaceutical industry is highly regulated both in the U.S. by the Food and Drug Administration ("FDA"), which must approve any drug before it is marketed and sold, and by local

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[1] All "Section" or "§" references are to sections of the Internal Revenue Code of 1986, as amended ("Code"), unless otherwise specified.

regulators in other jurisdictions.[2] As a result of the FDA's rigorous approval process, the average time between the original patent filing for a new drug and its launch in the U.S. market is approximately 13 years.[3] Effective tax policy that supports research and development ("R&D") and stimulates investment in innovation is vital to the success of our industry and creating new medicines for patients in need.

A perennial item of concern for BIO's members is the application of the Section 382 loss limitation rules.[4] These rules, which were amended significantly by the Tax Reform Act of 1986, are intended to counter "trafficking" in loss corporations. As described in greater detail below, the biotech R&D process generates tax losses as a primary byproduct. However, transactions involving early stage biotechs typically are not driven by loss trafficking considerations. It is the process of funding this R&D that often gives rise to Section 382 restrictions on the use of net operating loss ("NOL") carryforwards: the R&D can only be continued by raising capital in serial rounds of investment. This necessarily implicates Section 382, in situations where there is a stark mismatch in the timing of the generation of the NOLs in the R&D phase and the timing of the income associated with that R&D in the commercialization phase, which occurs many years later. In recent years, Treasury has promulgated regulations that provide additional flexibility to taxpayers under Section 382 where transactions do not bear "indicia of loss trafficking." *See* Treasury Decision 9638 (October 22, 2013) (exempting certain transactions involving the stock of loss corporations from the Section 382 segregation rules because they did not implicate the policies underlying Section 382). In contrast to this greater flexibility, BIO believes that the direction taken in Prop. Reg. § 1.382-7 represents an overly rigid exercise of regulatory authority to restrict the use of NOLs.

The proposed regulations would modify the calculation of net unrealized built in gain ("NUBIG"), net unrealized built in loss ("NUBIL"), recognized built-in gain ("RBIG"), and recognized built-in loss ("RBIL") in comparison to the calculation of such items under existing IRS guidance in Notice 2003-65, 2003-2 C.B. 747 (September 12, 2003). These changes, particularly Treasury's proposal to eliminate the so-called "Section 338 approach" for calculating RBIG, are highly relevant to BIO's emerging company members. The Section 338 approach can preserve additional NOLs from limitation under Section 382 when a loss corporation has a NUBIG. BIO's emerging companies are commonly established as C corporations and

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[2] In addition to the FDA, numerous other Federal, state, and local authorities have jurisdiction over, or enforce laws related to, the marketing and sale of drugs, including the U.S. Drug Enforcement Agency, the Centers for Medicare & Medicaid Services, the U.S. Department of Health and Human Services Office of Inspector General, the U.S. Department of Justice, state Attorneys General, state departments of health, and state pharmacy boards.

[3] Murray Aitken & Michael Kleinrock, *Lifetime Trends in Biopharmaceutical Innovation: Recent Evidence and Implications*, IQVIA, 4 (Jan. 2017).

[4] BIO submitted comments of items for inclusion on the 2018-2019 Priority Guidance Plan in which it recommended guidance on various Section 382 matters: fluctuation in value of multiple classes of stock, reliance on Securities and Exchange Commission filings by public companies to determine ownership changes, the treatment of restricted stockholders under Section 382, and safe harbors for capital contributions to loss corporations.

they generate significant NOL carryforwards in the course of their R&D activities. Discarding the Section 338 approach could significantly reduce the ability to use tax attributes of these companies, which can have an adverse impact on their ability to raise the capital required to fund their ongoing R&D. This letter sets forth BIO's comments with respect to the elimination of the Section 338 approach in Proposed Regulations § 1.382-7 and related matters.

Section 382 Ownership Change and Limitation

Under Section 382, a limitation is imposed on the use of NOLs and other tax attributes by a loss corporation that has undergone an ownership change. Section 383 applies a similar limitation to tax credits, such as the Orphan Drug Tax Credit under Section 45C, and other tax attributes in the event of an ownership change. In general, an ownership change occurs when there is a cumulative change in the loss corporation's ownership by "5-percent shareholders" (as defined in the Code) that exceeds 50 percentage points over a rolling testing period. A loss corporation that experiences an ownership change will generally be subject to an annual limitation on its subsequent use of NOL carryovers and other tax attributes that arose from pre-ownership change periods and use of losses that are subsequently recognized with respect to assets that had a built-in-loss on the date of the ownership change. The amount of the annual limitation generally equals the fair market value ("FMV") of the loss corporation immediately before the ownership change multiplied by the applicable long-term tax-exempt rate as defined in Section 382(f) (subject to certain adjustments). To the extent that the limitation in a post-ownership-change year is not fully utilized, the amount of the limitation for the succeeding year will be increased.

The current long-term tax-exempt rate is under 2%, which is substantially lower than the long-term tax-exempt rate of greater than 8% when Section 382 was amended to apply the foregoing formula. At that higher interest rate level, a company with a market capitalization that was similar in size to its current NOL carryforward could nevertheless potentially use all or nearly all of its NOLs over the carryforward period. Now, with such a substantially lower long-term tax-exempt interest rate, the NOL utilization of a company with a market cap similarly sized to its current NOL carryforward is significantly limited.[5]

As described more fully below, biotechs undertaking serial rounds of investment or mergers and acquisition ("M&A") transactions may be subject to the Section 382 loss limitation rules even though the transactions do not fit with Section 382's anti-

[5] Given that the NOL carryforward period for NOLs arising before the effective date of the Tax Cuts and Jobs Act ("TCJA") is limited to 20 years, denying use of the 338 method for these NOLs is particularly harsh for growing companies like biotechs as it means that, in many cases, significant NOLs may expire unused at the end of their carryforward period. For example, if the FMV of the loss corporation with a $100 million NOL were $100 million and the long-term tax-exempt rate were 10% (a level it approached in the mid-1980s, when Section 382 was revised to its current form), the Section 382 limitation would be $10 million per year without regard to the Section 382(h) built-in gain rules. Over a 10-year period, the aggregate Section 382 limitation would amount to $100 million, the full amount of the NOL. In contrast, at the current 2% long-term tax-exempt rate, only 20% of the NOL carryforward could be used over the same 10-year period and a substantial amount would expire unused at the end of the carryforward period.

abuse purposes. Biotechs generate losses on account of significant R&D activities that create new technologies – new medicines and therapies to treat diseases – and the long lead time between the commencement of R&D and the commercialization of a product results in a severe mismatch between the expenditures that create the technologies and the income resulting from the technology. In these cases, the application of the Section 382 limitation to such companies is punitive. Eliminating the Section 338 approach will only make it more so.

Section 382 Built-in Gain/Built-in Loss Rules

Section 382(h) addresses the treatment of the loss corporation's built-in gains and built-in losses as of the ownership change date. In general, a loss corporation may increase its Section 382 limitation by the amount of RBIG recognized during the five-year period beginning on the change date (the "recognition period"). Correspondingly, the RBILs recognized during the recognition period are subject to the Section 382 limitation similar to pre-change tax attributes. The increase to the Section 382 limitation on account of RBIG and the amount of built-in losses treated as RBILs is limited by the amount of NUBIG and NUBIL, respectively, as of the ownership change date.

NUBIG is calculated as the excess of the FMV of a loss corporation's assets immediately before an ownership change over the aggregate adjusted basis of its assets. NUBIL is calculated as the excess of the aggregate adjusted basis of the loss corporation's assets immediately before an ownership change over the FMV of a loss corporation's assets.[6] As explained by Treasury, the built-in gain/built-in loss rules were included to implement the "neutrality principle" underlying Section 382. The neutrality principle provides that a loss corporation's built-in gains and built-in losses, if recognized during the recognition period, are largely treated as if the built-in gains or built-in losses, as applicable, had been recognized before the ownership change.

Section 382(h) also takes into account built-in income items and built-in deduction items when calculating NUBIG/NUBIL/RBIG/RBIL. These are items of income or deduction that are properly taken into account during the recognition period, but are attributable to the pre-ownership change period. Thus, a built-in income item can, for example, increase NUBIG and RBIG. The statute provides little detail on how the built-in income and built-in deduction item rules operate.

Notice 2003-65

Notice 2003-65 provides guidance on the built-in income and built-in deduction rules with respect to (i) discharge of indebtedness income, (ii) contingent liabilities, (iii) bad debt deductions, and (iv) cost-recovery deductions. This Notice provides a safe harbor for the calculation of NUBIG/NUBIL and two safe harbors for the

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[6] Section 382(h)(3)(B) treats a loss corporation's NUBIG or NUBIL as zero if the amount does not exceed the lesser of (i) 15 percent of the FMV of the loss corporation's assets immediately before the ownership change, or (ii) $10,000,000.

calculation of RBIG/RBIL. The RBIG/RBIL safe harbors are the "Section 1374 approach" and the "Section 338 approach."[7]

The Section 1374 approach generally addresses built-in income and built-in deduction items using an accrual approach.[8]

The Section 338 approach operates by treating the gross assets of the company as if they were stepped up to their FMV in a hypothetical sale. The loss corporation then can increase its Section 382 limitation by an amount equal to a hypothetical depreciation/amortization of that stepped-up basis over a new depreciation or amortization period, less the actual depreciation/amortization being taken by the loss corporation. The Section 338 approach permits a loss corporation to increase its Section 382 limitation with RBIG without regard to the actual disposition of built-in gain assets.[9]

Preamble to the Proposed Regulations § 1.382-7

In the Preamble to the proposed regulations, Treasury has provided a discussion of current guidance applicable under Section 382(h) (Notice 87-79, 1987-2 C.B. 387, Notice 90-27, 1990-1 CB 336, Notice 2003-65 and Notice 2018-30, 2018-21 I.R.B. 610) and noted practitioner and other comments that have been made regarding the application of such guidance. The Preamble contains an extensive summary of the statutory built-in gain and built-in loss rules. Those rules are described herein where relevant to BIO's comments on Proposed Regulation § 1.382-7. The Preamble states:

> the Treasury Department and the IRS have concluded that the 338 approach lacks sufficient grounding in the statutory text of section 382(h). Further, the Treasury Department and the IRS have determined that the mechanics underlying the 338 approach (i) are inherently more complex than the accrual-based 1374 approach, (ii) can result in overstatements of RBIG and RBIL, and (iii) as a result of the TCJA, would require substantial modifications to eliminate increased uncertainty and ensure appropriate results. By eliminating the 338 approach, the Treasury Department and the IRS have determined that these proposed regulations would significantly reduce current and future complexity of section 382(h) computations for taxpayers and the IRS alike. The Treasury Department and the IRS

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[7] It has been noted that a rule of thumb is that the Section 338 approach under Notice 2003-65 should be utilized by companies with built-in gains and that the Section 1374 approach should be utilized by companies with built-in losses.

[8] BIO's comments primarily relate to the elimination of the Section 338 approach in the proposed regulations. For this reason, the Section 1374 approach is not discussed in depth in this comment letter.

[9] The underpinnings of this approach are that depreciable and amortizable assets (as well as depletable assets) are "wasting assets" that would generate income in later years. If the loss corporation had not undergone an ownership change, then that income would have been offset by its NOLs.

> welcome public comment on this proposed elimination of the 338 approach for determining RBIG and RBIL.

The Preamble goes on to state that the Section 338 approach has:

> significantly less grounding in the statutory text of section 382(h) than the 1374 approach. The comparatively tenuous connection between the 338 approach and the plain meaning of the statutory text of section 382(h) is exemplified by the method by which the 338 approach identifies RBIG. Under the 338 approach, depreciation deductions on certain built-in gain assets give rise to RBIG, even though no actual recognition of gain or income has occurred. However, sections 382(h)(2)(A) and 382(h)(6)(A) do not authorize RBIG treatment in the absence of actual gain or income recognized by the loss corporation.

Finally, the Preamble provides additional discussion of issues that could arise under the Section 338 approach related to the passage of the Tax Cuts and Jobs Act in 2017, including with respect to the treatment of built-in gain assets. With respect to those assets the Preamble states that using the Section 338 approach as a proxy for a realization event is problematic for two reasons:

> First, the schedules for cost recovery deductions were never intended to match the production of income from each asset; rather, they were intended to accelerate cost recovery to stimulate investment. Thus, this proxy is likely to, on average, overstate income created by those assets, further increasing NOL usage beyond the neutral baseline. Second, such an adjustment for income created by built-in gain assets is unnecessary, as it is already taken into account by section 382. Section 382 provides that the NOLs of the old loss corporation can be used by the new loss corporation up to the annual limit. This annual limit is equal to a prescribed interest rate multiplied by the value of the stock of the old loss corporation, and serves as a proxy for the income created by the assets of the old loss corporation. Thus, to the extent that the appreciated value of a built-in gain asset is reflected in the value of the stock, the general rule of section 382 allows for the NOLs of the old loss corporation to offset the flow of income created by that asset. Therefore, the treatment created by the 338 approach creates a double benefit. By eliminating this treatment, the proposed regulations reduce the attractiveness of inefficient, tax-motivated acquisitions, which enhances economic efficiency.

The proposed regulations implement the positions of Treasury and the IRS that are set forth in the Preamble.

Summary of Typical Biotech Scenario and Application of Section 382

BIO's members include many start-up/early stage companies that are heavily involved in entrepreneurial R&D of innovative healthcare, agricultural, industrial and environmental biotechnology products. These products ultimately will require FDA approval before the company is permitted to market and sell the product. This process often takes a decade or more during which time, the company will have no product revenue, but will be accumulating significant losses due to its extensive investment in R&D and creating many jobs.

Biotechs raise money in investment rounds that are tied to the need to obtain capital on a periodic basis to fund their R&D activities. These emerging companies are often organized as C corporations for tax purposes and have the following life-cycle: The founders capitalize the company using personal funds, "friends and family" and angel investor investments (seed funding). These funds support basic early-stage research that is intended to lead to the identification of a potential drug that can be tested in animals. In some cases, seed capital can cover the animal studies, but in others even seed capital is not enough. Eventually, biotechs will reach a point where they must conduct human clinical trials. This junction is often referred to as the "valley of death," where data from seed capital is not sufficient to attract investment from venture capitalists. If that valley of death can be crossed and additional funds raised, then the corporation will be in a position to submit an "IND" (an investigational new drug application) enabling preclinical studies and enter human trials. If the biotech can attract this venture investment, often referred to as "Series A financing," it can be in the form of preferred stock, which can have a multitude of features (preferred returns, liquidation preferences, convertibility into common stock, *etc.*) or common stock.[10] Subsequent rounds of investment can occur as the emerging company progresses through the clinical trial processes, demonstrating proof of concept that the drug is working in humans. Each round of financing only extends the cash runway to the next milestone. As a result, multiple rounds of additional financing are required each with the potential to trigger an ownership change. Investors at these stages are focused on clinical trial data value inflections and are not focused on obtaining NOL attributes.

If the company is successful in continuing its evolution of the business to the human clinical trial stage, there is often a significant shift in investor mix that may result in potential ownership change. These serial investments require the company to consider whether – and the extent to which – there may have been a change in the percentage ownership of the company that has resulted or may result in a

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[10] Important to note is that these emerging companies usually do not have access to traditional financing sources, such as commercial banks, although they may be able to raise additional funds from existing or potential equity investors by first issuing convertible debt instruments. The issuance of preferred stock and the potential volatility of the "pre-money" valuation in each investment round creates difficulty for BIO members in determining whether there has been an ownership change. BIO members must consider the "fluctuation in value" rules of Section 382(l)(3)(C) in computing the change in percentage ownership because they have issued different classes of stock. Treasury has issued some guidance on these fluctuation in value rules (Notice 2010-50, 2010-27 I.R.B. 12 (June 11, 2010)), although these can be extremely complicated to apply. As noted above, BIO has separately submitted comments regarding topics to be included on the Priority Guidance Plan requesting that Treasury consider possible ways to minimize the complexity of applying the fluctuation in value rules.

Section 382 ownership change. In addition to the foregoing sequence of events, other companies may encounter the application of Section 382 on account of M&A transactions. Biotechs are often acquired by larger companies in order to accelerate the regulatory process and commercial success of new medicines and these acquisitions directly implicate Section 382.[11]

Section 174 Deductions, NOLs and NUBIG

The tax position of start-up biotechs during the R&D phase generally follows a pattern. The company expends significant amounts on R&D and creating jobs, but generates little or no income (*i.e.*, they are "pre-revenue" companies). These R&D expenditures are immediately deductible under Section 174 and often times qualify for either the federal R&D credit or Orphan Drug Tax Credit. This generates NOLs (and credits as well) that may be carried forward under Section 172 to offset future income. These NOLs (and any credits) will be subject to limitation under Section 382 if there has been an ownership change.

In contrast to a distressed loss corporation scenario where Section 382 may apply to the NOLs of a company losing money because of a failing business, BIO members generate NOLs as their companies grow value. The deductibility of expenditures under Section 174 generates, as a corresponding feature, built-in gains in the loss corporation. This is because the company has little or no tax basis in its assets (assuming that an election has not been made to capitalize its Section 174 expenditures), but it has created valuable intellectual property (in the form of patent applications, patents, in-process R&D, and other self-created intangibles).[12] As a result, BIO members have had to consider the application of the built-in gain rules of Section 382(h) and Notice 2003-65 when they have undergone an ownership change because they have NUBIG.

The loss corporation's NUBIG provides the opportunity for the emerging company to free up additional NOLs under the Section 338 approach. The Section 382 limitation would be increased by the RBIG due to the Section 338 approach calculation and then that increased limitation would carryforward to later tax years (until a subsequent Section 382 ownership change occurs or the company becomes profitable and can use the NOLs). The potential for the increased Section 382 limitation and increased NOL carryforwards is a consideration for both the company and for current and future investors and/or acquirers. A reduction to the company's tax attributes, if the Section 338 approach no longer can be applied, would make the emerging company relatively less valuable. This can impact the willingness of existing and new investors to fund new investment, or the terms on which they are willing to invest.

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[11] These M&A transactions are not motivated by the existence of the biotech's NOLs and do not represent the types of "loss trafficking" transactions that Section 382 is intended to limit.

[12] A biotech will have self-created intangibles that are not considered Section 197 amortizable intangible assets and other intangibles that are amortizable under Section 197 on a straight line basis over 15 years.

While emerging companies are generally described as "pre-revenue," that does not mean that they do not have the potential to recognize taxable income or plans to do so in the future. Biotechs often enter into various types of transactions with other companies to expedite the drug approval process and commercial launch to provide new medicines to patients in need. For example, a biotech may enter into a licensing arrangement with a drug manufacturer that results in payments for intellectual property. These licensing arrangements may generate ordinary income (even though the company is pre-revenue) from an up-front payment or from the receipt of contingent payments tied to achieving various regulatory or other milestones.

For biotechs that choose to enter into joint ventures or retain full ownership and commercially launch its medicines the average time between the original patent filing for a new drug and its launch in the U.S. market is approximately 13 years.[13] Thus, even though biotechs may have limited current exposure to the payment of income taxes in early and mid-stage life cycles, they often times find themselves at certain points within their life cycle of earning taxable income. Any additional limitations on their NOLs can result in a cash tax liability for a company that has a history of extensive losses.

BIO Comments on Proposed Regulations § 1.382-7

BIO believes that the approach taken in the proposed regulations – taking away the option of applying the Section 338 approach – does not comport with sound tax policy. Loss corporations in the biotech industry already face significant headwinds in matching the deductions that lead to the development of the valuable R&D that creates products that help treat diseases with the taxable income that ultimately is earned from that R&D. The R&D and FDA approval process can take 10-12 years or longer, requires serial rounds of investment, and as a rule implicates the Section 382 ownership change rules. The Section 338 approach has, for the past 16 years, permitted these companies to preserve some additional portion of their NOLs. If that capability is no longer available, that will cause investors to reconsider the portion of their valuation taking into account tax benefits. As noted above, the changes to the NUBIG and RBIG calculations could further reduce the amount of NOL carryforwards available to offset taxable income. And, these changes to the rules could incentivize companies that have offshore affiliates to sell their intellectual property assets to those affiliates in order to use the NOLs before an ownership change or in order to generate RBIG.

BIO also believes that, while the mechanics of the Section 338 approach may present complexities, taxpayers have been addressing issues under Notice 2003-65 for well over a decade. This has permitted commentators to identify deficiencies and/or inconsistencies in the Section 338 approach, which deficiencies and inconsistencies can be addressed through current and future regulatory projects.

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[13] Murray Aitken & Michael Kleinrock, *Lifetime Trends in Biopharmaceutical Innovation: Recent Evidence and Implications*, IQVIA, 4 (Jan. 2017).

These types of regulatory projects can address issues such as the overstatement of RBIG and RBIL and legislative changes attributable to amendments to the Code.

Finally, BIO believes that other issues that are raised in the Preamble regarding the Section 338 approach are generally less applicable to biotechs. Many biotechs own substantial intangibles that would be amortized under Section 197 over a 15-year amortization period on a straight-line basis and are not typically involved in tax-motivated transactions.[14] Accordingly, the increase of RBIG attributable to the hypothetical depreciation/amortization amount under the Section 338 approach is unlikely to overstate income for a typical biotech because of a shorter depreciable/amortizable life. If there are issues with respect to the assets that have shorter useful lives, or on account of bonus depreciation and similar issues (as addressed in Notice 2018-30), that could be addressed through an alternative mechanism for calculating the relevant increase to RBIG.

BIO recommends the retention of the Section 338 approach in the final regulations.

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We appreciate your attention to the comments on Proposed Regulations § 1.382-7 set forth herein. Please feel free to contact me at (202) 962-9200 or BIO's outside tax counsel, James H. Combs of Honigman LLP, at (313) 465-7588.

Sincerely,

Cameron Arterton
Vice President, Tax Policy
Biotechnology Innovation Organization (BIO)

cc: Krishna P. Vallabhaneni, Tax Legislative Counsel, Department of the Treasury
Robert H. Wellen, Associate Chief Counsel (Corporate), IRS
Lisa Fuller, Deputy Associate Chief Counsel (Corporate), IRS
Kevin M. Jacobs, Senior Technician Reviewer (TCJA), IRS
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[14] The increase to the Section 382 limitation on account of RBIG attributable to the Section 338 approach may not result in an offset to a biotech's taxable income for many years. If the biotech does not have any income producing transactions (for example, because it is not approved to commercialize a product), the Section 338 approach will merely preserve a larger amount of NOL to be used in the future, without an immediate impact on cash taxes.